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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

PORTLAND DIVISION

CITY OF PORTLAND, OREGON

Plaintiff,

v.

AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; McKESSON CORPORATION; PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLS; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON

Case No.: 3:18-cv-817

COMPLAINT

Complaint for Public Nuisance; Violations of Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. § 1961 *et seq.*; Violations of 18 U.S.C. § 1962 *et seq.*; Negligence, Negligent Misrepresentation, and Negligence Per Se; Fraud and Fraudulent Misrepresentation; and Unjust Enrichment

DEMAND FOR JURY TRIAL

LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINCKRODT PLC and MALLINCKRODT LLC.

Defendants.

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Plaintiff, CITY OF PORTLAND, OREGON brings this Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt PLC; Mallinckrodt LLC; McKesson Corporation; Cardinal Health, Inc.; and AmerisourceBergen Drug Corporation (collectively "Defendants") and alleges as follows:

I. INTRODUCTION

1. Plaintiff brings this civil action to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance caused thereby, and to recoup monies that have been spent because of Defendants' false, deceptive and unfair marketing and/or unlawful diversion of prescription opioids.[1] Such economic damages were foreseeable to Defendants and were sustained because of Defendants' intentional and/or unlawful actions and omissions.

2. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid overdose deaths and addictions.[2]

[1] As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

[2] *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

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3. The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[3]

4. Plaintiff brings this suit against the manufacturers of prescription opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids, turning patients into drug addicts for their own corporate profit. Such actions were intentional and/or unlawful.

5. Plaintiff also brings this suit against the wholesale distributors of these highly addictive drugs. The distributors and manufacturers intentionally and/or unlawfully breached their legal duties under federal and state law to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates.

II. PARTIES

A. PLAINTIFF.

6. Plaintiff, CITY OF PORTLAND, OREGON, ("Portland" or "Plaintiff") is a public corporation, duly organized and existing by virtue of the laws of the State of Oregon, which may sue and plead in its own name. Or. Rev. Stat. §§ 221.020, 221.410; Portland City Charter §§ 1-101, 1-103.

7. Plaintiff has declared, *inter alia*, that opioid abuse, addiction, morbidity and mortality has created a serious public health and safety crisis, and is a public nuisance, and that

[3] *See* Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

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the diversion of legally produced controlled substances into the illicit market causes or contributes to this public nuisance.

8. The distribution and diversion of opioids into Oregon ("the State"), and into the City of Portland and surrounding areas (collectively, "Plaintiff's Community"), created the foreseeable opioid crisis and opioid public nuisance for which Plaintiff here seeks relief.

9. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which the Plaintiff seeks relief. Categories of past and continuing sustained damages include, *inter alia*,: (1) costs for providing medical care, additional therapeutic care, and prescription drug purchases, and other treatments for covered Health Plan Members suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling, rehabilitation services, and other supportive community services; (3) costs associated with law enforcement and public safety relating to the opioid epidemic. These damages have been suffered, and continue to be suffered directly, by the Plaintiff.

10. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

11. Plaintiff has standing to maintain an action on account of a public nuisance, as the Plaintiff has sustained injuries of a special character, distinct and different from that suffered by the public generally, as described in detail below. *City of Portland v. Boeing Company*, 179 F. Supp. 2d 1190, 1195 (D. Or. 2001).

12. Plaintiff has standing to recover damages incurred as a result of Defendants' actions and omissions. Plaintiff has standing to bring all claims pled herein, including, *inter alia*, to bring

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claims under the federal RICO statute, pursuant to 18 U.S.C. § 1961(3) ("persons" include entities that can hold legal title to property) and 18 U.S.C. § 1964 ("persons" have standing).

B. DEFENDANTS.

1. Manufacturer Defendants.

13. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

14. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY, INC. is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

15. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual nationwide sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers). Purdue transacts business in the State, targeting the State market for its products, including the opioids at issue in this lawsuit. Purdue directs advertising and informational materials

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as well as marketing and sales tactics to impact physicians and potential users of Purdue products within the State. Purdue has sustained, continuous business activity in the City of Portland, Oregon.

16. CEPHALON, INC. ("Cephalon, Inc.") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware corporation and is a wholly owned subsidiary of Teva Ltd. in Pennsylvania. Teva USA acquired Cephalon, Inc. in October 2011.

17. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[4] Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[5] In 2008, Cephalon, Inc. pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay $425 million.[6]

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[4] *Highlights of Prescribing Information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII* (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf.

[5] *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII* (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf.

[6] Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html.

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18. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon, Inc. products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon, Inc. in the United States through Teva USA and has done so since Teva USA's October 2011 acquisition of Cephalon, Inc. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon, Inc.-branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon, Inc. opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

19. All of Cephalon, Inc.'s promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.[7] Teva Ltd.'s financial reports list Cephalon, Inc.'s and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon, Inc. acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon, Inc.'s specialty sales," including *inter alia* sales of Fentora.[8] Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon, Inc. and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon, Inc. and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva

[7] *E.g.*, ACTIQ, http://www.actiq.com/ (displaying logo at bottom-left) (last visited Jan. 16, 2018).

[8] Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

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Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are hereinafter referred to collectively as "Cephalon."

20. Teva, Ltd, Teva USA, and Cephalon, Inc. work together to manufacture, promote, distribute and sell both brand name and generic versions of opioids nationally, and more particularly, in the City of Portland, Oregon. Cephalon transacts business in Oregon, targeting the Oregon market for its products, including the opioids at issue in this lawsuit. Cephalon directs advertising and informational materials as well as marketing and sales tactics to impact Oregon physicians and potential users of Cephalon products. Cephalon has sustained, continuous business activity in the City of Portland, Oregon.

21. JANSSEN PHARMACEUTICALS, INC. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. NORAMCO, INC. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as Janssen Pharmaceuticals, is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as Janssen Pharmaceuticals, is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen Pharmaceuticals' products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and its profits inure to J&J's benefit. Janssen Pharmaceuticals, Ortho-McNeil-Janssen Pharmaceuticals, Inc.,

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Janssen Pharmaceutica Inc., Noramco, and J&J are hereinafter referred to collectively as "Janssen."

22. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

23. Janssen has been engaged in the manufacture, promotion, distribution, and sale of opioids nationally, and more particularly, in the City of Portland, Oregon. Janssen transacts business in Oregon, targeting the Oregon market for its products, including the opioids at issue in this lawsuit. Janssen directs advertising and informational materials as well as marketing and sales tactics to impact Oregon physicians and potential users of Janssen products. Janssen has sustained, continuous business activity in the City of Portland, Oregon.

24. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are hereinafter referred to collectively as "Endo."

25. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and

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hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

26. Endo manufactures, promotes, distributes and sells opioids nationally and, more particularly, in the City of Portland, Oregon. Endo transacts business in Oregon, targeting the Oregon market for its products, including the opioids at issue in this lawsuit. Endo directs advertising and informational materials as well as marketing and sales tactics to impact Oregon physicians and potential users of Endo products. Endo has sustained, continuous business activity in the City of Portland, Oregon.

27. ALLERGAN PLC ("Allergan PLC") is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC ("Actavis PLC") acquired Allergan PLC in March 2015, and the combined company adopted a name change to Allergan PLC in June 2015. Before that, WATSON PHARMACEUTICALS, INC. ("Watson Pharmaceuticals") acquired ACTAVIS, INC. ("Actavis, Inc.") in October 2012, and the combined company adopted the name of Actavis, Inc. as of January 2013 and the name Actavis PLC as of October 2013. WATSON LABORATORIES, INC. ("Watson Laboratories") is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, PLC, f/k/a Watson Pharmaceuticals). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) ("Actavis Pharma") is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC ("Watson Pharma"). ACTAVIS LLC ("Actavis LLC") is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan PLC exercises control over these marketing and sales efforts and

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profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Allergan PLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Watson Pharmaceuticals, Watson Pharma, and Watson Laboratories are hereinafter referred to collectively as "Actavis."

28. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

29. Actavis transacts business in Oregon, targeting the Oregon market for its products, including the opioids at issue in this lawsuit. Actavis transacts business in Oregon, targeting the Oregon market for its products, including the opioids at issue in this lawsuit. Actavis directs advertising and informational materials as well as marketing and sales tactics to impact Oregon physicians and potential users of Actavis products. Actavis has sustained, continuous business activity in the City of Portland, Oregon.

30. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, PLC. Mallinckrodt, PLC and Mallinckrodt, LLC are hereinafter referred to collectively as "Mallinckrodt."

31. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. In July 2017 Mallinckrodt agreed to pay $35 million to settle allegations brought by the United States Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

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32. Mallinckrodt transacts business in Oregon, targeting the Oregon market for its products, including the opioids at issue in this lawsuit. Mallinckrodt directs advertising and informational materials as well as marketing and sales tactics to impact Oregon physicians and potential users of Mallinckrodt products. Mallinckrodt has sustained, continuous business activity in the City of Portland, Oregon.

2. Distributor Defendants.

33. The Distributor Defendants also are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in "wholesale distribution," as defined under state and federal law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing Plaintiff's Community.

34. McKESSON CORPORATION ("McKesson") at all relevant times, operated as a licensed distributor in Oregon, licensed by the Oregon State Board of Pharmacy. McKesson is a Delaware corporation. McKesson has its principal place of business located in San Francisco, California. McKesson does substantial business in Oregon wherein it distributes pharmaceuticals in the City of Portland. McKesson has sustained business activity in the City of Portland, Multnomah County, Oregon. McKesson has a distribution facility in Wilsonville, Oregon.

35. CARDINAL HEALTH, INC. ("Cardinal") at all relevant times, operated as a licensed distributor wholesaler in Oregon, licensed by the Oregon State Board of Pharmacy. Cardinal's principal office is located in Dublin, Ohio. Cardinal does substantial business in the

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State of Oregon, wherein it distributes pharmaceuticals in the City of Portland. Cardinal has sustained business activity in the City of Portland, Multnomah County, Oregon.

36. AMERISOURCEBERGEN DRUG CORPORATION ("AmerisourceBergen") at all relevant times, operated as a licensed distributor wholesaler in Oregon, licensed by the Oregon State Board of Pharmacy. AmerisourceBergen is a Delaware corporation and its principal place of business is located in Chesterbrook, Pennsylvania. AmerisourceBergen does substantial business in the State of Oregon wherein it distributes pharmaceuticals in the City of Portland. AmerisourceBergen has sustained business activity in the City of Portland, Multnomah County, Oregon.

37. The data which reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015). Neither the DEA[9] nor the wholesale distributors[10] will voluntarily disclose the data necessary to identify with specificity the transactions which will form the evidentiary basis for the claims asserted herein.

38. Consequently, Plaintiff has named the three (3) wholesale distributors (i.e., AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation) which dominate 85% of the market share for the distribution of prescription opioids. The "Big 3" are

[9] *See* Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit ("SARF"), FOI, Records Management Section ("SAR"), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ), *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 23) (filed 02/06/14) (noting that ARCOS data is "kept confidential by the DEA").

[10] *See* Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 93) (filed 11/02/16) ("Cardinal Health does not customarily release any of the information identified by the DEA's notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.").

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Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Drug Corporation predecessors). Each has been investigated and/or fined by the DEA for the failure to report suspicious orders. Plaintiff has reason to believe each has engaged in unlawful conduct, which resulted in the diversion of prescription opioids into Plaintiff's Community and that discovery will likely reveal others who likewise engaged in unlawful conduct. Plaintiff names each of the "Big 3" herein as defendants and places the industry on notice that the Plaintiff is acting to abate the public nuisance plaguing the community. Plaintiff will request expedited discovery pursuant to Rule 26(d) of the Federal Rules of Civil Procedure to secure the data necessary to reveal and/or confirm the identities of the wholesale distributors, including data from the ARCOS database.

III. JURISDICTION & VENUE

39. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq*. ("RICO"). This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

40. This Court also has jurisdiction over this action in accordance with 28 U.S.C. § 1332(a) because the Plaintiff is a "citizen" of this State, the named Defendants are citizens of different states and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

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41. This Court has personal jurisdiction over Defendants because they conduct business in the State, purposefully direct or directed their actions toward the State, some or all consented to be sued in the State by registering an agent for service of process, they consensually submitted to the jurisdiction of the State when obtaining a manufacturer or distributor license, and because they have the requisite minimum contacts with the State necessary to constitutionally permit the Court to exercise jurisdiction.

42. This Court also has personal jurisdiction over all of the defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial. *See, e.g.*, *Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796, 803 (N.D. Ohio 1998) (citing *LaSalle National Bank v. Arroyo Office Plaza, Ltd.,* 1988 WL 23824, *2 (N.D. Ill. Mar 10, 1988); *Butcher's Union Local No. 498 v. SDC Invest., Inc.*, 788 F.2d 535, 539 (9th Cir. 1986)).

43. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 18 U.S.C. §1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District. 28 U.S.C. § 1391(b); 18 U.S.C. §1965(a).

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IV. FACTUAL BACKGROUND

A. THE OPIOID EPIDEMIC.

1. The National Opioid Epidemic.

44. The past two decades have been characterized by increasing abuse and diversion of prescription drugs, including opioid medications, in the United States.[11]

45. Prescription opioids have become widely prescribed. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[12]

46. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses at epidemic levels. The News Release noted:

a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.

b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).

c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.

d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.

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[11] See Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

[12] Katherine M. Keyes at al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52 (2014).

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e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.

f. Almost 5,500 people start to misuse prescription painkillers every day.[13]

47. The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population.[14]

48. During the year 2000, outpatient retail pharmacies filled 174 million prescriptions for opioids nationwide. During 2009, they filled 83 million more.

49. Opioid prescriptions increased even as the percentage of patients visiting the doctor for pain remained constant.

50. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as Non-steroidal Anti-inflammatory Drug ("NSAID") and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.[15]

51. Approximately 20% of the population between the ages of 30 and 44 and nearly 30% of the population over 45 have used opioids. Indeed, "[o]pioids are the most common means of treatment for chronic pain."[16] From 1980 to 2000, opioid prescriptions for chronic pain visits doubled. This is the result not of an epidemic of pain, but an epidemic of prescribing. A study of 7.8 million doctor visits found that prescribing for pain increased by 73% between 2000 and 2010

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[13] *See* Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

[14] *See* Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

[15] Matthew Daubress et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States*, 2000-2010, 51 (10) Med. Care 870 (2013).

[16] Deborah Grady et al., *Opioids for Chronic Pain*, 171 (16) Arch. Intern. Med. 1426 (2011).

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– even though the number of office visits in which patients complained of pain did not change and prescribing of non-opioid pain medications decreased. For back pain alone – one of the most common chronic pain conditions – the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined and referrals to physical therapy remained steady.

52. This increase corresponds with, and was caused by, the Defendants' massive marketing push. The industry's spending nationwide on marketing of opioids stood at more than $20 million per quarter and $91 million annually in 2000. By 2011, that figure hit its peak of more than $70 million per quarter and $288 million annually, a more than three-fold increase. By 2014, the figures dropped to roughly $45 million per quarter and $182 million annually, as the Defendants confronted increased concern regarding opioid addiction, abuse, and diversion. Even so, the Defendants still spend double what they spent in 2000 on opioid marketing.

53. By far the largest component of this spending was opioid drug makers' detailing visits to individual doctors, with total detailing expenditures more than doubling between 2000 and 2014 and now standing at $168 million annually.

54. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than 21 percent over the 52,898 drug deaths recorded the previous year.[17]

[17] *See* Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Provisional Counts of Drug Overdose Deaths, (August 8, 2016), https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf.

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55. Moreover, the Centers for Disease Control and Prevention ("CDC") has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin.[18]

56. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.[19]

57. The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in four years. This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. ***Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use,*** specifically among persons who report past-year dependence or abuse. The increased availability of heroin, combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose.[20]

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[18] *See* Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html (last updated July 7, 2015).

[19] *See* Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016).

[20] *See* Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016).

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58. The societal costs of prescription drug abuse are "huge."[21]

59. Across the nation, local governments are struggling with a pernicious, ever-expanding epidemic of opioid addiction and abuse. Every day, more than 90 Americans lose their lives after overdosing on opioids.[22]

60. The National Institute on Drug Abuse identifies misuse and addiction to opioids as "a serious national crisis that affects public health as well as social and economic welfare."[23] The economic burden of prescription opioid misuse alone is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.[24]

61. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.[25]

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[21] *See* Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 [hereinafter Brief of HDMA].

[22] Opioid Crisis, NIH, National Institute on Drug Abuse (available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis (last visited Sept. 19, 2017) ("Opioid Crisis, NIH") (citing at note 1 Rudd RA, Seth P, David F, Scholl L, Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015, *MMWR MORB MORTAL WKLY REP.* 2016;65, doi:10.15585/mmwr.mm655051e1).

[23] Opioid Crisis, NIH.

[24] *Id.* (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013*, *MED CARE* 2016;54(10):901-906, doi:10.1097/MLR.0000000000000625).

[25] *See* Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 Morbidity & Mortality Wkly. Rep. 1445 (2016).

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62. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.[26]

63. Every day brings a new revelation regarding the depth of the opioid plague: just to name one example, the New York Times reported in September 2017 that the epidemic, which now claims 60,000 lives a year, is now killing babies and toddlers because ubiquitous, deadly opioids are "everywhere" and mistaken as candy.[27]

64. In 2016, the President of the United States declared an opioid and heroin epidemic.[28]

65. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country.[29] Meanwhile, the manufacturers and distributors of prescription opioids extract billions of dollars of revenue from the addicted American public while public entities experience hundreds of millions of dollars of injury – if not more – caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

66. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct is causing and/or contributing to the national, state, and local opioid epidemic.

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[26] *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

[27] Julie Turkewitz, *'The Pills are Everywhere': How the Opioid Crisis Claims Its Youngest Victims*, N.Y. Times, Sept. 20, 2017 ("'It's a cancer,' said [grandmother of dead one-year old], of the nation's opioid problem, 'with tendrils that are going everywhere.'").

[28] *See* Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").

[29] *See* Presidential Memorandum – Addressing Prescription Drug Abuse and Heroin Use, 2015 Daily Comp. Pres. Doc. 743 (Oct. 21, 2015), https://www.gpo.gov/fdsys/pkg/DCPD-201500743/pdf/DCPD-201500743.pdf.

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2. The Oregon Opioid Epidemic.

67. Oregon has been especially ravaged by the national opioid crisis.

68. In 2013, Oregon had more drug overdose deaths involving prescription opioids than any other type of drug.[30] Oregon's Prescription Drug Monitoring Program concluded that prescribed opioid use was pervasive among Oregonians, with 918,000 (almost 1 in 4 Oregonians) receiving a prescription for opioid medications in 2013.[31] A survey of data from 2012 to 2013 revealed that Oregon ranked 2nd among all states in non-medical use of prescription pain medication.[32]

69. In Oregon, the mortality rates due to heroin overdose increased from 0.8 per 100,000 in 2000 to 3.2 per 100,000 in 2013.[33]

70. From 2000 through 2014, 2,226 people in Oregon died due to prescription opioid overdose.[34] Oregon's unintentional and undetermined opioid poisoning deaths significantly increased over the years and peaked in 2006 at 238 deaths, a rate of 6.5 per 100,000.[35] The death

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[30] *See* Oregon Health Authority, *Oregon Prescription Drug Overdose, Misuse, and Dependency Prevention Plan,* November 18, 2015, available at http://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/prescription-drug-overdose-state-plan.pdf

[31] *Id.* at 7.

[32] *Id.* at 1.

[33] *Id.* at p. 7.

[34] *Id.* at p. 7.

[35] *Id.*

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rate in 2006 was a 364% increase from the death rate in 2000 (1.4 per 100,000).[36] In 2013, the death rate declined to 4.0 per 100,000, which was still 2.8 times higher than in 2000.[37]

71. According to the CDC, in 2016, 506 people died of drug overdoses in Oregon, for a rate of 11.9 per 100,000 people.[38] In 2015, 505 people died from drug overdoses in Oregon while in 2014, 522 people died.[39] In contrast, in 2005, 386 people died from drug overdoses in Oregon and in 1999 that number was just 210 people.[40]

72. Between 2000 and 2012, 15,230 people were hospitalized in Oregon due to an unintentional and undetermined drug overdose.[41] The number of opioid-related hospitalizations in Oregon steadily increased from 2000 to 2014. In 2000, there were 2.6 hospitalizations per 100,000 people.[42] The rate of opioid-related hospitalizations reached a peak of 11.7 per 100,000 people in 2011 and in 2014 had decreased to 9.6 per 100,000 people.[43]

73. Neonatal Abstinence Syndrome (NAS), a collection of symptoms newborn babies experience withdrawing from opioid medications taken by the mother, increased dramatically in

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[36] *Id.* at 8.

[37] *Id.*

[38] *See* https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm at "2016 Deaths" tab.

[39] *Id.* at "2015 Deaths" tab and "2014 Deaths" tab.

[40] *Id.* at "20005 Deaths" tab and "1999 Deaths" tab.

[41] *See* Oregon Health Authority 2014 *Drug Overdose Deaths, Hospitalizations, Abuse & Dependency among Oregonians* at p. 6, available at http://www.oregon.gov/oha/PH/DiseasesConditions/InjuryFatalityData/Documents/oregon-drug-overdose-report.pdf.

[42] *See http://www.oregon.gov/oha/ph/preventionwellness/substanceuse/opioids/pages/data.aspx.*

[43] *Id.*

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Oregon between 1999 and 2013 from 1.0 per 1,000 hospital births in 2000 to 5.0 per 1,000 in 2013.[44]

3. The Opioid Epidemic in Plaintiff's Community.

i. Opioid overdoses have had significant impacts and costs in Plaintiff's Community.

74. In 2013, the City of Portland had 21 overdose death investigations.[45] The number of overdose death investigations increased to 37 in 2015.[46]

75. The City of Portland is in Multnomah County, Oregon. The population of the City of Portland makes up approximately 79% percent of the total population of Multnomah County.[47]

76. In 2015, there were over 600 overdose responses in Clackamas and Multnomah County, with 88% occurring in Multnomah County.[48] While opioid deaths in the region have declined since the peak in 2011-2012, the progress in preventing fatal overdoses has slowed.[49]

77. Between 2009 and 2015, there were a total of 861 opioid-related deaths in Multnomah County.[50]

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[44] Jean Y. Ko, et al., *Incidence of Neonatal Abstinence Syndrome — 28 States, 1999-2013*, 65 Morbidity & Mortality Wkly. Rep. 799 (2016).

[45] *See* https://www.portlandoregon.gov/police/article/34023.

[46] *Id.*

[47] In the 2010 census, Portland had a population of 583,766 and Multnomah County had a population of 735,334. *See* https://www.census.gov/quickfacts/fact/table/portlandcityoregon/PST045216? and https://www.census.gov/quickfacts/fact/table/multnomahcountyoregon/PST045216.

[48] *See* 2016 Tri-County Region Opioid Trends – Clackamas, Multnomah, and Washington, Oregon, available at https://portlandprofessional.oregonpainguidance.org/wp-content/uploads/sites/8/2017/02/TRI-COUNTY-REGION-OPIOID-TRENDS-2016-REPORT.pdf.

[49] *Id.*

[50] *Id.* at p. 5.

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78. Multnomah County's rate of hospitalization encounters involving opioid poisoning has been among the highest in the State and has more than doubled from 2000 to 2014. The rate of overdose hospitalizations involving opioids for Multnomah County residents from 2000 to 2004 was 6.8 per 100,000 residents.[51] From 2005 to 2009, the rate of overdose hospitalizations involving opioids was 13.21 per 100,000 residents.[52] From 2010 to 2014, the rate of overdose hospitalizations involving opioids was 15 per 100,000 residents.[53]

79. Additionally, Multnomah County's rate of EMS response to opioid-overdose calls was particularly high in 2013 through 2015. In 2013, Multnomah County EMS responded to opioid overdoses at a rate of 87 calls per 100,000 residents.[54] In 2014, the Multnomah County EMS responded to opioid overdoses at a rate of 94 calls per 100,000 residents.[55] In 2015, the response rate decreased to 73 calls per 100,000 residents; however, it is possible that the decrease may be due to the increase in law enforcement personnel and lay people carrying and administering naloxone.[56]

80. The Portland Fire and Rescue Bureau ("PF&R") provides emergency medical services throughout the City of Portland. A considerable number first responder calls in Portland are responded to by PF&R.

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[51] *See* http://www.oregon.gov/oha/ph/preventionwellness/substanceuse/opioids/pages/data.aspx.

[52] *Id.*

[53] *Id.*

[54] *See* 2016 Tri-County Region Opioid Trends, at p. 15-17, available at https://portlandprofessional.oregonpainguidance.org/wp-content/uploads/sites/8/2017/02/TRI-COUNTY-REGION-OPIOID-TRENDS-2016-REPORT.pdf.

[55] *Id.*

[56] *Id.*

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81. In 2016, PF&R responded to 3,475 calls for overdoses and administered 408 doses of naloxone.

82. In 2017, PF&R responded to 3,800 calls for overdoses and administered 445 doses of naloxone.

83. Some Portland Police Bureau officers also carry and administer naloxone.

84. PF&R trains its members and administers training for other bureaus on the use of naloxone.

85. Approximately 50% of the drug-related cases and calls addressed by the Portland Police Bureaus' drugs and vice division in 2017 involved heroin or other opioids.

86. Portland Police Bureau administers the Service Coordination Team, which is designed to reduce incidences of drug-related property crime and reduce the cycle of criminality and drug addiction. In fiscal year 2016-2017, 39% of participants in this program indicated heroin or other opioids as their "drug of choice," which was an increase from 29% in fiscal year 2015-2016.

87. An estimated 37.5% of Portland's unsheltered population self-report a substance abuse disorder.[57] The City of Portland contributes millions of dollars annually toward programming for housing and homelessness. This programming includes supportive housing that provides treatment for substance abuse disorders.

[57] 2017 Point-In-Time Count of Homelessness in Portland/Gresham/Multnomah, County Oregon, Portland State University (October 2017), available at https://static1.squarespace.com/static/566631e8c21b864679fff4de/t/59ee2e7a5ffd207c6e7b41a0/1508781707710/PSU+2017+Point-In-Time_FINAL_%28Interactive%29+%281%29+%281%29.pdf.

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ii. Prescriptions for Opioids have substantially increased in Plaintiff's Community.

88. The CDC has tracked prescription opioid rates per county in the United States.[58] According to data compiled by the CDC, the prescribing rate in Multnomah County, as demonstrated in the chart below, increased between 2006 and 2008, where it peaked, but continues to be high. Throughout the ten-year period, the prescription rate has exceeded any legitimate medical, scientific, or industrial purpose.

Retail Opioid Prescriptions Dispensed per 100 Persons		
Year	Multnomah County	United States[59]
2006	81.9[60]	72.4
2007	86.4[61]	75.9
2008	87.8[62]	78.2
2009	82.9[63]	79.5
2010	81.2[64]	81.2

[58] U.S. Prescribing Rate Maps, CDC, available at https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html (last visited Mar. 29, 2018).

[59] *Id*.

[60] U.S. County Prescribing Rates, 2006, CDC, available at https://www.cdc.gov/drugoverdose/maps/rxcounty2006.html (last visited Mar. 31, 2018).

[61] U.S. County Prescribing Rates, 2007, CDC, available at https://www.cdc.gov/drugoverdose/maps/rxcounty2007.html (last visited Mar. 31, 2018).

[62] U.S. County Prescribing Rates, 2008, CDC, available at https://www.cdc.gov/drugoverdose/maps/rxcounty2008.html (last visited Mar. 31, 2018).

[63] U.S. County Prescribing Rates, 2009, CDC, available at https://www.cdc.gov/drugoverdose/maps/rxcounty2009.html (last visited Mar. 31, 2018).

[64] U.S. County Prescribing Rates, 2010, CDC, available at https://www.cdc.gov/drugoverdose/maps/rxcounty2010.html (last visited Mar. 31, 2018).

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2011	78.8[65]	80.9
2012	72.9[66]	81.3
2013	68.5[67]	78.1
2014	65.3[68]	75.6
2015	57.8[69]	70.6
2016	51.3[70]	66.5

89. The sheer volume of these dangerously addictive drugs was destined to create the present crisis of addiction, abuse, and overdose deaths.

iii. Plaintiff has incurred increased costs resulting from payment through self-insured healthcare plans and workers compensation for opioid-prescriptions and related medical expenses.

90. Plaintiff was damaged directly, through its payments of claims for chronic opioid therapy by (a) its self-insured health care plans and (b) its self-insured workers' compensation program (including the City of Portland's Fire and Police Disability and Retirement).

[65] U.S. County Prescribing Rates, 2011, CDC, available at https://www.cdc.gov/drugoverdose/maps/rxcounty2011.html (last visited Mar. 31, 2018).

[66] U.S. County Prescribing Rates, 2012, CDC, available at https://www.cdc.gov/drugoverdose/maps/rxcounty2012.html (last visited Mar. 31, 2018).

[67] U.S. County Prescribing Rates, 2013, CDC, available at https://www.cdc.gov/drugoverdose/maps/rxcounty2013.html (last visited Mar. 31, 2018).

[68] U.S. County Prescribing Rates, 2014, CDC, available at https://www.cdc.gov/drugoverdose/maps/rxcounty2014.html (last visited Mar. 31, 2018).

[69] U.S. County Prescribing Rates, 2015, CDC, available at https://www.cdc.gov/drugoverdose/maps/rxcounty2015.html (last visited Mar. 31, 2018).

[70] Centers for Disease Control and Prevention, U.S. County Prescribing Rates 2016, (reporting for "Multnomah, OR," here and below) available https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html (last visited Mar. 29, 2018).

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91. The Defendants' marketing of opioids caused health care providers to prescribe and Plaintiff, through its health plans and workers' compensation program, to pay for prescriptions of opioids to treat chronic pain. Because of the Defendants' unbranded marketing, health care providers wrote and Plaintiff paid for prescription opioids for chronic pain that were filled not only with their drugs, but with opioids sold by other manufacturers. All of these prescriptions were caused by Defendants' fraudulent marketing and therefore all of them constitute false claims. Because, as laid out below, Plaintiff is obligated to cover medically necessary and reasonably required care, it had no choice but to pay these claims.

92. The fact that Plaintiff would pay for these prescriptions is both the foreseeable and intended consequence of the Defendants' fraudulent and negligent marketing scheme. The Defendants set out to change the medical and general consensus supporting chronic opioid therapy *so that* doctors would prescribe and government payors, such as Plaintiff, would pay for long-term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

93. Upon information and belief, a review of Plaintiff's reimbursements related to opioid prescriptions, and the costs associated with those prescriptions, will show that as the Defendants spent more to promote their drugs, doctors began prescribing them more often and as a result, the costs to Plaintiff went up.

94. It is also alarming (and a sign of further problems ahead) that the drop in national opioid prescribing beginning in 2014 has been accompanied by a corresponding increase in the Defendants' promotional spending, which is headed towards a new high, despite evidence of the grave toll that opioids are taking on law enforcement, public health, and individual lives.

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95. Plaintiff asserts that each Defendant made misrepresentations directly or by omission of material facts by their employees, agents, or co-conspirators to prescribing physicians who then wrote opioid prescriptions for which Plaintiff paid. Furthermore, Plaintiff asserts that specific details about the names of the employees, agents, or co-conspirators, the substance of the misrepresentations or omissions, the time and date and location of said misrepresentations or omissions, and the names of the prescribing physicians who were exposed to each Defendants' misrepresentations or omissions were closely tracked by the Defendants, are in the exclusive possession of the Defendants, and Plaintiff reasonably believes that such information will be disclosed in discovery.

1. Health Care Plans

96. Plaintiff provides comprehensive health care benefits, including prescription drugs coverage, to its employees, self-pay participants, and their eligible dependents ("Health Plan Members"). These benefits are provided under Plaintiff's health plans. Plaintiff self-insures one of its health plans, which has the majority of Plaintiff's enrollees.

97. The prescription drug plan under Plaintiff's self-insured health plan is also self-insured: the costs of prescription drugs are paid directly by Plaintiff.

98. Throughout the relevant time period for this action, the self-insured health plan's prescription drug costs have been paid by Plaintiff.

99. Doctors submit claims directly to Plaintiff's applicable pharmacy benefit manager contracted as part of its self-insured health plan for their costs associated with prescribing opioids, including office visits and toxicology screens for patients prescribed opioids. In addition, prescriptions for opioids written by these doctors for patients covered by Plaintiff's self-insured health plan are filled by pharmacies, which submit claims for reimbursement to Plaintiff's third-party claims administrators.

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100. Plaintiff's applicable health plan provides benefits for all "medically necessary" services associated with opioids, including treatment related to any adverse outcomes from chronic opioid therapy, such as overdose or addiction treatment.

101. Defendants caused doctors and pharmacies to submit, and Plaintiff to pay, claims to its self-insured health plan that were not appropriate for reimbursement by: (a) causing doctors to write prescriptions for chronic opioid therapy based on deceptive representations regarding the risks, benefits, and superiority of those drugs; (b) causing doctors to certify that these prescriptions and associated services were medically necessary; (c) causing claims to be submitted for drugs that were promoted for off-label uses and misbranded, and therefore not FDA-approved; and (d) distorting the standard of care for treatment of chronic pain so that doctors would feel not only that it was appropriate, but required, that they prescribe and continue prescriptions for opioids long-term to treat chronic pain.

102. Plaintiff's self-insured health plans only cover the cost of prescription drugs that are medically necessary and dispensed for a FDA-approved purpose. Prescriptions drugs that are not medically necessary or that are dispensed for a non-FDA approved purpose are expressly excluded from coverage under Plaintiff's plans. Under the City's health plans a treatment is medically necessary if it "the care must be provided for the diagnosis or direct care and treatment of a medical condition, sickness, disease, injury, or bodily malfunction."

103. In-network doctors who care for Health Plan Members are bound by the provider agreements that entitle them to participate in Plaintiff's health plan. These agreements generally permit doctors to charge only for treatments that are medically necessary.

104. Plaintiff is obligated to pay for the medically necessary treatment of covered Health Plan Members.

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105. In prescribing opioids for chronic pain, doctors certify that the treatment is medically necessary and the drugs dispensed for an FDA approved purpose, and – at least with respect to the self-insured plan – the health plan authorizes payment from Plaintiff's funds.

106. As described above, the use of opioids to treat chronic pain is not "in accordance with generally accepted standards of medical practice" nor "clinically appropriate . . . and considered effective for the patient's illness, injury or disease."

107. Further, the Defendants' deceptive marketing rendered opioids misbranded as prescribed for chronic pain because they were false and misleading and because, by minimizing the risks associated with the drugs, they did not contain adequate directions for use. The written, printed, or graphic matter accompanying the Defendants' drugs did not accurately describe the risks associated with long-term use of their products, rendering them misbranded. Due to this misbranding, the Defendants' opioids were not FDA-approved, within the meaning of Plaintiff's self-insured health plan, for the long-term treatment of chronic pain.

108. For each and all of the reasons above, Plaintiff should not have been responsible for reimbursing claims for prescription drugs that were not medically necessary.

109. As a result of the Defendants' deceptive marketing, Plaintiff's Health Plan Members who used opioids long-term to treat chronic pain also incurred additional costs and suffered additional injuries requiring care, including doctors' visits, toxicology screens, hospitalization for overdoses, treatment and other adverse effects of opioids, and long-term disability, among others, which caused Plaintiff to incur additional costs.

110. The costs incurred by Plaintiff include, but are not limited to, doctor visits, which would also be included with these prescriptions. This includes prescriptions that also were caused by Defendants' deceptive marketing, including prescriptions for Defendants' generic opioid

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products and prescriptions for opioids from other manufacturers. The costs incurred also include the cost to Plaintiff of prescribing opioids, such as doctors' visits or toxicology screens, or the costs of treating the adverse effects of prescribing opioids long-term, such as overdose and addiction. They also do not reflect the total damages for all years to Plaintiff, which will be determined at trial, and which will include costs to the health plan for the treatment of opioid abuse and dependency.

111. The claims – and the attendant and consequential costs – for opioids prescribed for chronic pain, as opposed to acute and cancer or end-of-life pain, were improperly paid as the result of the Defendants' deceptive and unfair conduct.

2. Workers' Compensation Programs

112. Plaintiff, through a self-insured program, provides workers' compensation, including prescription drug benefits, to eligible employees injured in the course of their employment. When an employee is injured on the job, he or she may file a claim for workers' compensation. If the injury is deemed work-related, Plaintiff is responsible for paying the employee's medical costs and lost wages.

113. Doctors submit claims to Plaintiff's workers' compensation program for the costs associated with prescribing opioids, including office visits and toxicology screens for patients prescribed opioids.

114. Plaintiff's workers' compensation program covers all costs associated with opioids, and may include treatment related to any adverse outcomes from chronic opioid therapy, such as addiction treatment.

115. The Defendants caused doctors and pharmacies to submit, and Plaintiff to pay, claims to its workers' compensation program that were inappropriate by: (a) causing doctors to write prescriptions for chronic opioid therapy based on deceptive representations regarding the risks,

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benefits, and superiority of those drugs; (b) causing doctors to certify that these prescriptions and associated services were medically necessary; (c) causing claims to be submitted for drugs that were promoted for off-label uses and misbranded, and therefore not FDA-approved; and (d) distorting the standard of care for treatment of chronic pain so that doctors would feel not only that it was appropriate, but required, that they prescribe and continue prescriptions for opioids long-term to treat chronic pain.

116. In prescribing opioids for chronic pain, doctors certify that the treatment is medically necessary and reasonably required, and the workers' compensation program authorizes payment from Plaintiff funds.

117. Plaintiff's workers' compensation program is obligated to cover all "medically necessary" and "reasonably required" treatment arising from a compensable work-related injury.

118. As described above, however, the use of opioids to treat chronic pain is not medically necessary or reasonably required in that their risks do not materially exceed their benefits; they do not improve physiological function; and their use is not consistent with guidelines that are *scientifically based* (as opposed to marketing driven).

119. Nevertheless, the amount of such prescriptions paid by worker's compensation programs is monumental. A study of the National Council on Compensation Insurance ("NCCI") concluded that, in 2011, approximately 38% of pharmacy costs in workers' compensation are for opioids and opioid combinations, amounting to approximately $1.4 billion.

120. Plaintiff incurred costs associated with prescribing opioids, such as doctors' visits or toxicology screens, or the costs of treating the adverse effects of prescribing opioids long-term such as overdose and addiction.

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121. However, the costs of long-term opioid use are not limited to costs of opioid prescriptions. Long-term opioid use is accompanied by a host of consequential costs, including costs related to abuse, addiction, and death.

122. These claims – and their attendant and consequential costs – for opioids prescribed for chronic pain, as opposed to acute and cancer or end-of-life pain, were the result of the Defendants' fraudulent scheme.

B. THE MANUFACTURER DEFENDANTS' FALSE, DECEPTIVE, AND UNFAIR MARKETING OF OPIOIDS.

123. The opioid epidemic did not happen by accident.

124. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

125. Each Manufacturer Defendant has conducted, and has continued to conduct, a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

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126. The Manufacturer Defendants have made false and misleading claims, contrary to the language on their drugs' labels, regarding the risks of using their drugs that: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. The Manufacturer Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

127. The Manufacturer Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded front groups.

128. The Manufacturer Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.[71] In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon

[71] *See* Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, Fortune, Nov. 9, 2011, http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/; David Crow,

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General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[72] This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

129. The Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

1. Each Manufacturer Defendant Used Multiple Avenues to Disseminate Their False and Deceptive Statements about Opioids.

130. The Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in and around the State, including in Plaintiff's Community. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State and Plaintiff's Community.

131. The Manufacturer Defendants employed the same marketing plans and strategies and deployed the same messages in and around the State, including in Plaintiff's Community, as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and

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Drugmakers Hooked on $10bn Opioid Habit, Fin. Times, Aug. 10, 2016, https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95.

[72] Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), http://turnthetiderx.org/.

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overseen on a national basis by corporate headquarters. This comprehensive approach ensures that the Manufacturer Defendants' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

132. The Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks and sales training materials; and nationally coordinated advertising. The Manufacturer Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to check on both their performance and compliance.

iv. Direct Marketing.

133. The Manufacturer Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Manufacturer Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, upon information and belief, the Manufacturer Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

134. Many of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker, chef, and teacher, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Upon information and

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belief, Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

135. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. The Manufacturer Defendants have not corrected this misinformation. Instead, each Defendant devoted massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, the Manufacturer Defendants spent in excess of $168 million on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

136. The Manufacturer Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, the Manufacturer Defendants purchase, manipulate and analyze some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, the Manufacturer Defendants know their detailing to doctors is effective.

137. The Manufacturer Defendants' detailers have been reprimanded for their deceptive promotions. In March 2010, for example, the FDA found that Actavis had been distributing promotional materials that "minimize[] the risks associated with Kadian and misleadingly suggest[] that Kadian is safer than has been demonstrated." Those materials in particular "fail to

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reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed."[73]

v. Indirect Marketing.

138. The Manufacturer Defendants indirectly marketed their opioids using unbranded advertising, paid speakers and "key opinion leaders" ("KOLs"), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups").

139. The Manufacturer Defendants deceptively marketed opioids in the State and Plaintiff's Community through unbranded advertising – e.g., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Manufacturer Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, the Manufacturer Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, Continuing Medical Education ("CME") programs, and medical conferences and seminars. To this end, the Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

[73] Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

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140. The Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, the Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long term opioid use for chronic pain.

141. Manufacturer Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Manufacturer Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Manufacturer Defendants. Upon information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids.

142. Borrowing a page from Big Tobacco's playbook, the Manufacturer Defendants worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors who served as KOLs, and (b) funding, assisting, directing, and encouraging seemingly neutral and credible Front Groups. The Manufacturer Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, CME programs, medical conferences and

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seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, the Manufacturer Defendants persuaded doctors and patients that what they have long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and that the compassionate treatment of pain required opioids.

143. In 2007, multiple states sued Purdue for engaging in unfair and deceptive practices in its marketing, promotion, and sale of OxyContin. Certain states settled their claims in a series of Consent Judgments that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the future. By using indirect marketing strategies, however, Purdue intentionally circumvented these restrictions. Such actions include contributing to the creation of misleading publications and prescribing guidelines that lack reliable scientific basis, and promoting prescribing practices that have worsened the opioid crisis.

144. Pro-opioid doctors are one of the most important avenues that the Manufacturer Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website "In the Face of Pain" failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

145. Manufacturer Defendants utilized many KOLs, including many of the same ones.

146. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the

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Manufacturer Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by the Manufacturer Defendants.

147. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low."[74] He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[75]

148. Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal

[74] Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

[75] Good Morning America, ABC television broadcast (Aug. 30, 2010).

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was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[76] Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[77]

149. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President of the AAPM in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants (including nearly $2 million from Cephalon).

150. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

151. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to this screening appear in various industry-

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[76] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

[77] *Id.*

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supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into their own guidelines, indicating, also, their reliance on the Manufacturer Defendants and those under their influence and control.

152. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors in the State and doctors treating members of Plaintiff's Community.[78]

153. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain*—a book that is still available online—when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."[79] Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed

[78] *See* Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

[79] Lynn Webster & Beth Dove, Avoiding Opioid Abuse While Managing Pain, 59 (2007).

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himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[80]

154. The Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the Manufacturer Defendants, these Front Groups generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted the Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

155. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. The Manufacturer Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, the Manufacturer Defendants made sure that the Front Groups would generate only the messages that the Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

156. Defendants Cephalon, Endo, Janssen, and Purdue, in particular, utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society

[80] John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html.

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("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), the Center for Practical Bioethics ("CPB"), the U.S. Pain Foundation ("USPF") and Pain & Policy Studies Group ("PPSG").[81]

157. The most prominent of the Manufacturer Defendants' Front Groups was the American Pain Foundation ("APF"), which, upon information and belief, received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012, primarily from Endo and Purdue. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach residents of the State and Plaintiff's Community.

158. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, upon information and belief, APF was entirely dependent

[81] *See generally, e.g.*, Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015), https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf.

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on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit.

159. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. Upon information and belief, it was often called upon to provide "patient representatives" for the Manufacturer Defendants' promotional activities, including for Purdue's Partners Against Pain and Janssen's Let's Talk Pain. APF functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients. Indeed, upon information and belief, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

160. On information and belief, on several occasions, representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

161. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and the Manufacturer Defendants stopped funding it. Within days

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of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[82]

162. Another front group for the Manufacturer Defendants was the American Academy of Pain Medicine ("AAPM"). With the assistance, prompting, involvement, and funding of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

163. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.[83]

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[82] Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies' Ties to Pain Groups*, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

[83] The American Academy of Pain Medicine, *Pain Medicine DC The Governing Voices of Pain: Medicine, Science, and Government*, March 24-27, 2011, http://www.painmed.org/files/2011-annual-meeting-program-book.pdf.

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164. Upon information and belief, AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

165. The Manufacturer Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

166. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and, upon information and belief, was taken down from AAPM's website only after a doctor complained.[84]

167. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.[85] Treatment guidelines have been relied upon by doctors, especially the general practitioners and family doctors targeted by the Manufacturer Defendants. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in

[84] *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997).

[85] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

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determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

168. At least fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.[86] One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids. The Guidelines have been cited hundreds of times in academic literature, were disseminated in the State and/or Plaintiff's Community during the relevant time period, are still available online, and were reprinted in the Journal of Pain. The Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the Manufacturer Defendants' financial support to members of the panel.

169. The Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example,

[86] *Id.*

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Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Manufacturer Defendants determined would reduce prescribing.

2. The Manufacturer Defendants' Marketing Scheme Misrepresented the Risks and Benefits of Opioids.

i. The Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair assurances, grossly understating and misstating the dangerous addiction risks of the opioid drugs.

170. To falsely assure physicians and patients that opioids are safe, the Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted, and because those at greatest risk for addiction could be identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. The Manufacturer Defendants have not only failed to correct these misrepresentations, they continue to make them today.

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171. Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint. Yet even afterward, each Manufacturer Defendant continued to misrepresent the risks and benefits of long-term opioid use in the State and Plaintiff's Community and each continues to fail to correct its past misrepresentations.

172. Some illustrative examples of the Manufacturer Defendants' false, deceptive, and unfair claims about the purportedly low risk of addiction include:

a. Actavis's predecessor caused a patient education brochure, *Managing Chronic Back Pain*, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which suggested that "[p]eople with the disease of addiction" may abuse opioids by unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.[87]

c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

d. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health

[87] Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last visited Mar. 8, 2018).

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care providers who treat people with pain agree that most people do not develop an addiction problem."

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are always addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." Although the term "rarely" is not defined, the overall presentation suggests the risk is so low as not to be a worry. The language also implies that as long as a prescription is given, opioid use is not a problem.

f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction." This publication is still available online.[88]

h. In 2010, Mallinckrodt sponsored an initiative "Collaborating and Acting Responsibly to Ensure Safety" (C.A.R.E.S.), through which it published and promoted the book "Defeat Chronic Pain Now!" aimed at chronic pain patients. The book, which is still available for sale in New Mexico and elsewhere, and is promoted online at www.defeatchronicpainnow.com, advises laypeople who are considering taking opioid drugs that "[o]nly rarely does opioid medication cause a true addiction."[89] Further, the book advises that even the issue of tolerance is "overblown," because "[o]nly a minority of chronic pain patients who are taking long-term opioids develop tolerance." In response to a hypothetical question from a chronic back pain patient who expresses a fear of becoming addicted, the book advises that "[i]t is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

i. Consistent with the Manufacturer Defendants' published marketing materials, upon information and belief, detailers for Purdue, Endo, Janssen, and Cephalon in the State and Plaintiff's Community minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with

[88] Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*], http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[89] Charles E. Argoff & Bradley S. Galer, *Defeat Chronic Pain Now!* (2010).

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purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.[90]

173. These claims are contrary to longstanding scientific evidence. A 2016 opioid-prescription guideline issued by the CDC (the "2016 CDC Guideline") explains that there is "[e]xtensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .)."[91] The 2016 CDC Guideline further explains that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[92]

174. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting ("ER/LA") opioids in 2013 and for immediate release ("IR") opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with

[90] Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

[91] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[92] *Id.* at 2, 25.

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long-term opioid use, including "risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death," extended-release opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed.[93]

175. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder."[94] Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State of New York found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in this State.

176. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, the Manufacturer Defendants also fostered a fundamental misunderstanding of the signs

[93] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf.; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf.

[94] Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at 16, https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

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of addiction. Specifically, the Manufacturer Defendants misrepresented, to doctors and patients, that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (i.e., pseudoaddiction) – and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

177. To this end, one of Purdue's employees, Dr. David Haddox, invented a phenomenon called "pseudoaddiction." KOL Dr. Portenoy popularized the term. Examples of the false, misleading, deceptive, and unfair statements regarding pseudoaddiction include:

a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction.[95] The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.[96] Purdue spent over $100,000 to support distribution of the book. Cephalon spent $150,000 to purchase copies of the book in bulk and distributed it through its pain sales force to 10,000 prescribers and 5,000 pharmacists. Endo spent $246,620 to buy copies of FSMB's *Responsible Opioid Prescribing* (2007), which was distributed by Endo's sales force.

b. Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

c. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which, upon information and belief, promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which, upon information and belief, described pseudoaddiction as a concept that

[95] Scott M. Fishman, M.D., Responsible Opioid Prescribing: A Physician's Guide (2007) at 62.

[96] *See* Scott M. Fishman, M.D., Responsible Opioid Prescribing: A Physician's Guide, at 31 (2d ed. 2012).

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"emerged in the literature to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

e. Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse." In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

f. "Defeat Chronic Pain Now!" teaches laypeople that "pseudoaddiction" is "caused by their doctor not appropriately prescribing the opioid medication." It teaches that "[p]seudoaddiction happens when a patient's opioid medication is not being prescribed in doses strong enough to provide good pain relief, or if the drug is not being prescribed often enough throughout the day. . . When a pseudoaddicted patient is prescribed the proper amount of opioid medication, he or she doesn't take any extra pills because his or her pain is relieved."

178. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudoaddiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already addicted patients.

179. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, a third category of false, deceptive, and unfair practice is the Manufacturer Defendants' false instructions that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

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a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers' bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. Purdue, upon information and belief, sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

c. As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

180. The 2016 CDC Guideline confirms the falsity of these claims. The Guideline explains that there are no studies assessing the effectiveness of risk mitigation strategies "for improving outcomes related to overdose, addiction, abuse, or misuse."[97]

181. A fourth category of deceptive messaging regarding dangerous opioids is the Manufacturer Defendants' false assurances regarding the alleged ease of eliminating opioid dependence. The Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use. In truth, the 2016 CDC Guideline explains that the symptoms of opioid withdrawal include abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia, drug cravings, anxiety, insomnia, spontaneous abortion and premature labor in pregnant women.[98]

[97] 2016 CDC Guideline at 11

[98] 2016 CDC Guideline at 26

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182. The Manufacturer Defendants nonetheless downplayed the severity of opioid detoxification. For example, upon information and belief, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.[99] Similarly, in the 2010 Mallinckrodt/C.A.R.E.S. publication "Defeat Chronic Pain Now!" potential opioid users are advised that tolerance to opioids is "easily remedied," and that "[a]ll patients can be safely taken off opioid medication if the dose is slowly tapered down by their doctor."

183. A fifth category of false, deceptive, and unfair statements the Manufacturer Defendants made to sell more drugs is that opioid dosages could be increased indefinitely without added risk. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. The Manufacturer Defendants' deceptive claims include:

a. Upon information and belief, Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis appears to have continued to use these materials in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of

[99] Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*], http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf., at 32.

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an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain. The guide also claimed that some patients "need" a larger dose of the drug, regardless of the dose currently prescribed. This language fails to disclose heightened risks at elevated doses. This publication is still available online.

c. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."[100]

d. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

e. Upon information and belief, Purdue's "In the Face of Pain" website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

f. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," and that "the need for higher doses of medication is not necessarily indicative of addiction," but inaccurately downplayed the risks from high opioid dosages. This publication is still available online.[101]

g. In 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

h. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, "the oldest and largest organization in the US dedicated to advancing a scientific

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[100] Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesic*s, Endo Pharmaceuticals (2004), https://www.yumpu.com/en/document/view/35479278/understanding-your-pain-taking-oral-opioid-analgesics (last visited Mar. 8, 2018).

[101] Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*], http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf., at 32.

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approach to substance use and addictive disorders,"[102] challenging the correlation between opioid dosage and overdose.

i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.[103]

j. In the 2010 Mallinckrodt/C.A.R.E.S. publication "Defeat Chronic Pain Now!", potential opioid users are warned about the risk of "[p]seudoaddiction [b]ecause of a [l]ow [d]ose," and advised that this condition may be corrected through the prescription of a higher dose. Similarly, the book recommends that for chronic pain patients, the opioid dose should be "gradually increased to find the best daily dose, as is done with all the other oral drugs." The book discusses the risks of NSAIDs and other drugs at higher doses, but not explain this risk for opioids.

184. Once again, the 2016 CDC Guideline reveals that the Manufacturer Defendants' representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."[104] More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."[105] The CDC also states that there is an increased risk "for opioid use disorder, respiratory depression, and death at higher dosages."[106] That is why the CDC advises doctors to "avoid increasing dosage" to above 90 morphine milligram equivalents per day.[107]

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[102] The College on Problems of Drug Dependence, *About the College*, http://cpdd.org (last visited Aug. 21, 2017).

[103] Brief of APF, at 9.

[104] 2016 CDC Guideline at 22–23.

[105] *Id.* at 23–24.

[106] *Id.* at 21.

[107] *Id.* at 16.

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185. Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can cure addiction and abuse.

186. The Manufacturer Defendants made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets' "extended-release features can be compromised, causing the medication to 'dose dump,' when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing."[108] Also troubling, Opana ER can be prepared for snorting using commonly available methods and "readily prepared for injection."[109] The letter discussed "the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection."[110] Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Opana ER be removed from the market.

ii. The Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair assurances, grossly overstating the benefits of the opioid drugs.

187. To convince doctors and patients that opioids should be used to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-

[108] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

[109] *Id.* at 6.

[110] *Id.* at 6 n.21.

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term opioid use. But as the CDC Guideline makes clear, "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)," and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[111] The FDA, too, has recognized the lack of evidence to support long-term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

188. Some illustrative examples of the Manufacturer Defendants' false claims are:

a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

d. Janssen promoted Ultracet for everyday chronic pain and distributed posters, for display in doctors' offices, of presumed patients in active professions; the caption read, "Pain doesn't fit into their schedules."

e. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

f. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.

[111] *Id.* at 15.

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g. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."[112] The *Treatment Options* guide notes that non-steroidal anti-inflammatory drugs have greater risks with prolonged duration of use, but there was no similar warning for opioids. This publication is still available online. APF distributed 17,200 copies in one year alone, according to its 2007 annual report.

h. Endo's NIPC website "PainKnowledge" claimed in 2009, upon information and belief, that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

i. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient."[113] Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

j. Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the "Let's Talk Pain" campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."

k. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health," and "[o]verall health-related quality of life for chronic pain."[114] The Policymaker's Guide was originally published in 2011.

l. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

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[112] APF, *Treatment Options*, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

[113] *E.g.*, NIPC, *Persistent Pain and the Older Patient* (2007), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4372897/.

[114] Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*], http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf., at 29.

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189. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature.

190. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that "we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in an overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[115] And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

191. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for extended-release and long-acting ("ER/LA") opioids in 2013 and immediate-release ("IR") opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back

[115] Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

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pain.[116] Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

192. Purdue's competitors were aware of this problem. For example, upon information and belief, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Upon information and belief, Purdue's sales representatives continue to tell doctors that OxyContin lasts a full 12 hours.

193. Front Groups supported by Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Ohio by the American Pain

[116] 2016 CDC Guideline at 12.

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Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

> OxyContin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleep through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, OxyContin has been a miracle medication.[117]

194. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.[118] Specifically, the FDA advised that

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[117] Reply Brief of Amicus Curiae of the American Pain Foundation, The National Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting Appellants, *Howland v. Purdue Pharma L.P.*, No. 2003-1538 (Ohio Apr. 13, 2004), 2004 WL 1637768, at *4 (footnote omitted).

[118] *See* U.S. Food & Drug Admin., *Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets)* (Sept. 26, 2007), https://wayback.archive-it.org/7993/20170406045231/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm

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Fentora "is only approved for breakthrough cancer pain in patients who are *opioid-tolerant,* meaning those patients who take a regular, daily, around-the-clock narcotic pain medicine."[119]

195. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, and for which it is not safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

a. Cephalon paid to have its sponsored CME, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "[c]linically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.

b. Upon information and belief, Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

c. In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

196. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

197. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have

[119] *Id.*

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maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report that a Los Angeles clinic prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described it internally as "an organized drug ring" until years after law enforcement shut it down. In doing so, Purdue protected its own profits at the expense of public health and safety.[120]

198. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to

[120] Harriet Ryan et al., *More Than 1 Million Oxycontin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, http://www.latimes.com/projects/la-me-oxycontin-part2/.

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prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.[121]

3. The Manufacturer Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations.

199. As a part of their deceptive marketing scheme, the Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including this State and Plaintiff's Community. For example, the Manufacturer Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept the Manufacturer Defendants' misrepresentations.

200. The Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. The Manufacturer Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids may suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages.[122] The 2016 CDC Guideline concludes that there must be "additional caution and increased monitoring"

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[121] Press Release, Attorney General Eric T. Schneiderman, A.G. Schneiderman Announces Settlement With Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing of Prescription Opioid Drugs (Mar. 3, 2016), https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals (last visited Mar. 9, 2018).

[122] 2016 CDC Guideline at 13.

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to minimize the risks of opioid use in elderly patients.[123] The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

4. The Manufacturer Defendants Made Materially Deceptive Statements and Concealed Material Facts.

201. As alleged herein, the Manufacturer Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids. The Manufacturer Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

202. Defendant Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

[123] *Id.* at 27.

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e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

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q. Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing; and

r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

203. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;

d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations – including over $5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

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i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

204. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and

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approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

205. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

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a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

j. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

206. Defendant Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

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c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

5. The Manufacturer Defendants Fraudulently Concealed Their Misconduct.

207. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience establish that opioids are highly addictive and are responsible for a long list of very serious adverse outcomes. The FDA warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and death – all of which clearly described the harm from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered into agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

208. At all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and deceptive statements about the risks and

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benefits of long-term opioid use for chronic pain. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own role.

209. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The lack of support for the Manufacturer Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by the Plaintiff or Plaintiff's Community. Thus, the Manufacturer Defendants successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the claims that

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the Plaintiff now asserts. Plaintiff did not know of the existence or scope of the Manufacturer Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

C. THE DISTRIBUTOR DEFENDANTS' UNLAWFUL DISTRIBUTION OF OPIOIDS.

210. The Distributor Defendants owe a duty under federal law (21 U.S.C. § 823, 21 CFR 1301.74) to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Plaintiff's Community as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted into Plaintiff's Community.

211. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

212. Each Distributor Defendant repeatedly and purposefully breached its duties under state and federal law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes into Plaintiff's Community.

213. The unlawful diversion of prescription opioids is a direct and proximate cause and/or substantial contributing factor to the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the State and in Plaintiff's Community. This diversion and the epidemic are direct causes of harms for which Plaintiff seeks to recover here.

214. The opioid epidemic in the State, including *inter alia* in Plaintiff's Community, remains an immediate ***hazard to public health and safety***.

215. The opioid epidemic in Plaintiff's Community is a temporary and continuous ***public nuisance*** and remains unabated.

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216. The Distributor Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

1. Wholesale Drug Distributors Have a Duty under State and Federal Law to Guard Against, and Report, Unlawful Diversion and to Report and Prevent Suspicious Orders.

217. As under federal law, opioids are a Schedule II controlled substance under Oregon law. *See* Or. Admin. Code § 855-080-0022, Or. Rev. Stat. § 475.035. Opioids are categorized as "Schedule II" drugs because they have a "high potential for abuse" and the potential to cause "severe psychic or physical dependence" and/or "severe psychological . . . dependence." 21 U.S.C. § 812(b)(2)(A)-(C).

218. Oregon law required Defendants to register with the Oregon Board of Pharmacy. Or. Rev. Stat. §475.125(1). *See also* Or. Rev. Stat. § 475.005 *et seq.* (Oregon Uniform Controlled Substances Act); Or. Rev. Stat. § 689.205 (providing State Board of Pharmacy with the authority to make rules deemed necessary for the proper administration and enforcement of this chapter); Or. Rev. Stat. § 689.155 (setting forth the State Board of Pharmacy's responsibilities in regard to medications, drugs, etc.); Or. Rev. Stat. § 689.315 (providing the State Board of Pharmacy with the authority to specify rules and registration procedures for licensing of manufacturers and wholesalers); Or. Admin. Code § 855-065-0006(1) (registration requirements for wholesale distributors); Or. Admin. Code § 855-065-0007 (minimum qualifications for wholesale distributors); Or. Admin. Code § 855-065-0010 (minimum requirements for reporting, record keeping and inventory management for wholesale distributors); Or. Admin. Code § 855-065-0012 (storage of drug requirements); and Or. Admin. Code § 855-065-0013 (prohibited practices of wholesale distributors).

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219. The Oregon Board of Pharmacy has the authority to suspend or revoke a registration to manufacture, deliver or dispense a controlled substance upon a finding that the registrant: "has furnished false or fraudulent material information in any application"; "has had the federal registration suspended or revoked"; or "has violated any rule of the board"; "has failed to maintain proper records"; or "continuance of registration would be inconsistent with the public interest under any factor stated in ORS 475.135." Or. Rev. Stat. § 475.145. In determining the public interest, the State Board of Pharmacy considers several factors, including, "failure to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels"; and "failure to comply with applicable state or local laws." Or. Rev. Stat. § 475.135.

220. A "manufacturer or wholesaler may not sell or otherwise distribute, or offer to sell or otherwise distribute, any drug or device except to a person legally authorized to resell, dispense or otherwise redistribute such drug or device." Or. Rev. Stat. § 689.527(7).

221. The Oregon State Board of Pharmacy Regulations require that "a wholesale distributor must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs." Furthermore, Oregon law incorporates federal requirements set out under the Controlled Substance Act and related controlled substance laws and regulations, "[t]hese records must comply with all federal drug laws and regulations." Or. Admin. Code § 855-065-0010(1); *see also* Or. Rev. Stat. § 689.155. Wholesale Distributors "must establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, transport, shipping and distribution of drugs, including policies and procedures for identifying, recording, and reporting any loss, theft, counterfeiting or diversion of any drug and for correcting all errors and inaccuracies in inventories." Or. Admin. Code § 855-065-0010(5).

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222. A wholesale distributor "involved in the distribution of controlled substances . . . must register with the Drug Enforcement Administration and the Board, and comply with all laws related to the storage, handling, transport, shipment, and distribution of controlled substances." Or. Admin. Code § 855-065-0010(8). As of July 2017, a wholesale distributor "must notify the Board in writing of suspicious orders of controlled substances to be distributed within Oregon upon discovery. Suspicious orders include, but are not limited to orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." Or. Admin. Code § 855-065-0010(9).

223. Each Distributor Defendant was further required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Oregon law adopts and incorporates those requirements, as set out above. *See, e.g.*, Or. Admin. Code § 855-065-0010.

224. Each Distributor Defendant has an affirmative duty under federal and Oregon law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1); Or. Admin. Code § 855-065-0010(9). Oregon law requires that all locations "for each facility at which drugs are received, stored, warehoused, handled, held, offered, marketed" shall meet security standards including "safeguards against theft and diversion" Or. Admin. Code § 855-065-0012.

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225. The Oregon State Board of Pharmacy, in determining the qualifications for registration, considers whether "granting the registration is not consistent with the public health or safety or is otherwise not in the public interest." Or. Admin. Code § 855-065-0007(7).

226. Federal regulations and Oregon law impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). *See also* Or. Admin. Code § 855-065-0010(9). ("A wholesale distribut[o]r must notify the Board in writing of suspicious orders of controlled substances to be distributed within Oregon upon discovery.").

227. "Suspicious orders" include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. *See* 21 CFR 1301.74(b). *See also* Or. Admin. Code § 855-065-0010(9). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

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228. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. *Id.*

229. These prescription drugs are regulated for the purpose of providing a "closed" system **intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market**, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[124]

230. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities.[125]

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[124] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

[125] Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HDA, *About*, https://www.healthcaredistribution.org/about (last visited Aug. 21, 2017). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, https://www.nacds.org/ about/mission/ (last visited Aug. 21, 2017).

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231. As the DEA advised the Distributor Defendants in a letter dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[126]

232. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.[127]

233. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, ***in addition*** to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[128] The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to

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[126] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

[127] *See* Brief for HDMA and NACDS, 2016 WL 1321983, at *4 ("[R]egulations . . . in place for more than 40 years require distributors to *report* suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").

[128] Rannazzisi Letter, at 2.

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deliver controlled substances only for lawful purposes."[129] The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[130]

234. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.[131] This letter reminds the Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[132] The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.
>
> The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.

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[129] *Id.* at 1.

[130] *Id.* at 2.

[131] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

[132] *Id.*

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> Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.
>
> When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."
>
> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.[133]

Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[134]

235. The Distributor Defendants admit that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."[135]

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[133] *Id.*

[134] *Id.*

[135] *See* Brief of HDMA, 2012 WL 1637016, at *2.

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236. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[136]

237. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Plaintiff's Community and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to Plaintiff's Community.

238. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

239. Each Distributor Defendant owes a duty under federal and state law to investigate and refuse suspicious orders of prescription opioids.

240. Each Distributor Defendant owes a duty under federal and state law to report suspicious orders of prescription opioids.

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[136] Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

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241. Each Distributor Defendant owes a duty under federal and state law to prevent the diversion of prescription opioids into illicit markets in the State and Plaintiff's Community.

242. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction.

243. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in Plaintiff's Community and the damages caused thereby.

2. The Distributor Defendants Breached Their Duties.

244. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.[137]

245. The sheer volume of prescription opioids distributed to pharmacies in Plaintiff's Community, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted into Plaintiff's community, is excessive for the medical need and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[138]

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[137] *See* Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

[138] *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,316, 62,322 (2012)).

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246. The Distributor Defendants failed to report "suspicious orders" originating from Plaintiff's Community, or which the Distributor Defendants knew were likely to be diverted to Plaintiff's Community, to the federal and state authorities, including the DEA and/or the state Board of Pharmacy.

247. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Plaintiff's Community, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

248. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates originating from Plaintiff's Community, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

249. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

250. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal and state law.

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251. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.[139]

252. The federal and state laws at issue here are public safety laws.

253. The Distributor Defendants supplied prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

254. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by federal and state law which are required to legally acquire and maintain a license to distribute prescription opiates.

255. The Distributor Defendants acted with actual malice in breaching their duties, *i.e.*, they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

256. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others.

3. The Distributor Defendants Have Sought to Avoid and Have Misrepresented Their Compliance with Their Legal Duties.

257. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under state and federal law and have wrongfully and repeatedly disavowed those

[139] *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

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duties in an effort to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

258. Distributor Defendants have refused to recognize any duty beyond *reporting* suspicious orders. In *Masters Pharmaceuticals*, the HDMA, a trade association run by the Distributor Defendants, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows**:**

a. The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled."[140]

b. The Associations argued that, "DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgement of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligations on distributors threatens to disrupt patient access to needed prescription medications."[141]

c. The Associations alleged (inaccurately) that nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious."[142]

d. The Association complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties."[143]

[140] Brief for HDMA and NACDS, 2016 WL 1321983, at *4–5.

[141] *Id.* at *8 (citations and quotation marks omitted).

[142] *Id.* at *14.

[143] *Id.* at *22.

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e. The Associations alleged (inaccurately) that "DEA's regulations [] sensibly impose[] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders."[144]

f. Also, inaccurately, the Associations argued that, "[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands."[145]

259. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.[146]

260. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." *Id*. at 212. Master Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. *Id.* at 218–19, 226. A distributor's investigation must dispel all the red flags giving rise to suspicious circumstances prior to shipping a suspicious order. *Id*. at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id*. at 220.

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[144] *Id.* at *24–25.

[145] *Id.* at *26.

[146] *See* Brief of HDMA, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").

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261. Wholesale Distributor McKesson has recently been forced to specifically admit to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[147] Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[148] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq*., at the McKesson Distribution Centers."[149] Due to these violations, McKesson agreed that

[147] *See* Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), https://www.justice.gov/opa/press-release/file/928476/download.

[148] *Id.* at 4.

[149] *Id.*

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its authority to distribute controlled substances from numerous facilities would be partially suspended.[150]

262. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.[151] In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed to do so.[152] The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."[153] As a result of these violations, McKesson was fined and required to pay to the United States $150,000,000.[154]

263. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

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[150] *Id.* at 6.

[151] *Id.* at 4.

[152] *Id.*

[153] *Id.*; *see also* Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017)[hereinafter 2017 Settlement Agreement and Release] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), https://www.justice.gov/opa/press-release/file/928471/download.

[154] *See* 2017 Settlement Agreement and Release, at 6.

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264. Because of the Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.[155] The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[156] These actions include the following:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center

[155] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

[156] *Id.*

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("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center;

j. On May 14, 2012, Cardinal Health entered into an Administrative Memorandum of Agreement with the DEA in which, among other things, Cardinal Health "admits that its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate," and

k. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

265. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the

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DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to cure any violations of law before a suspension order can be issued.[157]

266. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

267. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[158] Given the

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[157] *See* Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html.

[158] Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html.

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sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results.

268. Similarly, Defendant McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[159] Again, given McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

269. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. The Plaintiff did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

270. Meanwhile, the opioid epidemic rages unabated in the Nation, the State, and in Plaintiff's Community.

271. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

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[159] Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

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272. The wrongful actions and omissions of the Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's racketeering allegations below.

273. The Distributor Defendants have abandoned their duties imposed under federal and state law, taken advantage of a lack of DEA law enforcement, and abused the privilege of distributing controlled substances in the State and Plaintiff's Community.

D. THE MANUFACTURER DEFENDANTS' UNLAWFUL FAILURE TO PREVENT DIVERSION AND MONITOR, REPORT, AND PREVENT SUSPICIOUS ORDERS.

274. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under federal and Oregon law.

275. Under Oregon and federal law, the Manufacturing Defendants were required to comply with the same licensing requirements as the Distributor Defendants and the same rules regarding prevention of diversion and reporting suspicious orders, as set out above. *See* Or. Rev. Stat. Ann. § 689.315 (providing the State Board of Pharmacy with the authority to specify rules and registration procedures for licensing of manufacturers and wholesalers). The Oregon Board of Pharmacy has the authority to "suspend or revoke" a registration issued to a manufacture, deliver or dispense a controlled substance upon a finding that the registrant: "has furnished false or fraudulent material information in any application"; "has had the federal registration suspended or revoked"; or "has violated any rule of the board"; "has failed to maintain proper records"; or "continuation of registration would be inconsistent with the public interest under any factor stated in ORS 475.135." Or. Rev. Stat. Ann. § 475.145. In determining the public interest, the State Board

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of Pharmacy considers several factors, including, "failure to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels"; and "failure to comply with applicable state or local laws." Or. Rev. Stat. Ann. § 475.135. *See also*, Or. Admin. Code § 855-060-0004 ("any person that manufactures or contracts for the manufacture of a drug or prescription device that is intended for sale, distribution, dispensing or administration in Oregon must register with the Oregon Board of Pharmacy.")

276. Like the Distributor Defendants, the Manufacturer Defendants were required to register with the DEA to manufacture schedule II controlled substances, like prescription opioids. *See* 21 U.S.C. § 823(a). A requirement of such registration is the:

> maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes

21 U.S.C. § 823(a)(1) (emphasis added).

277. Additionally, as "registrants" under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74. *See also* 21 C.F.R. § 1301.02 ("Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter."); 21 C.F.R. § 1300.01 ("Registrant means any person who is registered pursuant to either section 303

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or section 1008 of the Act (21 U.S.C. 823 or 958)." Like the Distributor Defendants, the Manufacture Defendants breached these duties.

278. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

279. Federal statutes and regulations – and Oregon law incorporating those requirements – are clear: just like opioid distributors, opioid manufacturers are required to "design and operate a system to disclose . . . suspicious orders of controlled substances" and to maintain "effective controls against diversion." 21 C.F.R. § 1301.74; 21 U.S.C. § 823(a)(1).

280. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[160]

[160] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for

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281. In the press release accompanying the settlement, the Department of Justice stated: Mallinckrodt "did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . 'Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . .'"[161]

282. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[162]

283. The Memorandum of Agreement entered into by Mallinckrodt ("2017 Mallinckrodt MOA") avers "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[163]

Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

[161] *Id.* (quoting DEA Acting Administrator Chuck Rosenberg).

[162] *Id.*

[163] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC

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284. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

> With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:
>
> i. conduct adequate due diligence of its customers;
> ii. detect and report to the DEA orders of unusual size and frequency;
> iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
> 1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
> 2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and
> 3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;
> iv. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and
> v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[164]

285. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion

(July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download ("2017 Mallinckrodt MOA").

[164] 2017 Mallinckrodt MOA at 2-3.

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Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[165]

286. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants." Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[166]

287. The same duties imposed by federal law on Mallinckrodt were imposed upon all Manufacturer Defendants.

288. The same business practices utilized by Mallinckrodt regarding "charge backs" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Manufacturer Defendants.

289. Through, *inter alia*, the charge back data, the Manufacturer Defendants could monitor suspicious orders of opioids.

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[165] *Id.* at 3-4.

[166] *Id.* at 5.

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290. The Manufacturer Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal and state law.

291. The Manufacturer Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

292. The Manufacturer Defendants have misrepresented their compliance with federal and state law.

293. The Manufacturer Defendants enabled the supply of prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

294. The wrongful actions and omissions of the Manufacturer Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's racketeering allegations below.

295. The Manufacturer Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into Plaintiff's Community.

E. DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF LEGAL DUTIES CAUSED THE HARM ALLEGED HEREIN AND SUBSTANTIAL DAMAGES.

296. As the Manufacturer Defendants' efforts to expand the market for opioids increased so have the rates of prescription and sale of their products — and the rates of opioid-related substance abuse, hospitalization, and death among the people of the State and the Plaintiff's Community. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids into Plaintiff's Community, fueling the epidemic.

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297. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[167]

298. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[168]

299. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[169]

300. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.[170]

301. As shown above, the opioid epidemic has escalated in Plaintiff's Community with devastating effects. Substantial opiate-related substance abuse, hospitalization and death mirrors Defendants' increased distribution of opiates.

302. Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids, like heroin, the massive distribution of opioids to Plaintiff's Community and areas from which such opioids are being diverted into Plaintiff's Community, has caused the Defendant-caused opioid epidemic to include heroin addiction, abuse, and death.

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[167] *See* Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

[168] *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

[169] *See* Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

[170] *See* Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

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303. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in the State and in Plaintiff's Community.

304. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in the State and in Plaintiff's Community.

305. Defendants repeatedly and purposefully breached their duties under state and federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes into the Plaintiff's Community.

306. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the State and Plaintiff's Community. This diversion and the epidemic are direct causes of foreseeable harms incurred by the Plaintiff and Plaintiff's Community.

307. Defendants' intentional and/or unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiff seeks relief, as alleged herein. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

308. Plaintiff seeks economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

309. Plaintiff seeks economic damages from the Defendants to pay for the cost to permanently eliminate the hazards to public health and safety and abate the temporary public nuisance.

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310. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."[171]

311. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.[172]

312. These community-based problems require community-based solutions that have been limited by "budgetary constraints at the state and Federal levels."[173]

313. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon the Plaintiff and Plaintiff's Community.

F. STATUTES OF LIMITATIONS ARE TOLLED AND DEFENDANTS ARE ESTOPPED FROM ASSERTED STATUTES OF LIMITATIONS AS DEFENSES.

1. Continuing Conduct.

314. Plaintiff continues to suffer harm from the unlawful actions by the Defendants.

315. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed, nor have all the damages been incurred, until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has

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[171] *See* Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016), at 1145.

[172] *See* Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al. eds., 2015), http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf.

[173] *See* Office of Nat'l Drug Control Policy, Exec. Office of the President, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* (2011), https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf.

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not ceased. The public nuisance remains unabated. The conduct causing the damages remains unabated.

2. Equitable Estoppel.

316. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive Plaintiff and to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State, the Plaintiff, and Plaintiff's Community, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. As described in the allegations set forth above, the Defendants affirmatively assured the public, including the State, the Plaintiff, and Plaintiff's Community, that they are working to curb the opioid epidemic.

317. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[174]

318. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[175]

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[174] Bernstein et al., *supra*.

[175] Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

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319. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associations, HDMA and NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[176]

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

b. "DEA regulations that have been in place for more than 40 years require distributors to *report* suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders)."

c. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

d. "A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy."

e. "Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash."

Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

320. The Distributor Defendants have also concealed and prevented discovery of information, including data from the ARCOS database that will confirm their identities and the extent of their wrongful and illegal activities.

321. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer

[176] Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, *25.

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Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The medical community, consumers, the State, and Plaintiff's Community were duped by the Manufacturer Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State and in Plaintiff's Community.

322. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff and Plaintiff's Community. Plaintiff and Plaintiff's Community did not know, and did not have the means to know, the truth due to Defendants' actions and omissions.

323. The Plaintiff and Plaintiff's Community reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders. To the extent statutes of limitations could apply to Plaintiff's claims, Plaintiff failed to commence an action within the statutory periods because of reliance on Defendants' wrongful conduct.

324. Defendants are estopped from asserting a statute of limitations defense because their conduct and misrepresentations were so unfair and misleading as to outweigh the public's interest in setting limitations on bringing actions.

325. The purposes of the statutes of limitations period, if any, are satisfied because Defendants cannot claim prejudice due to a late filing where the Plaintiff filed suit promptly upon

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discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

LEGAL CAUSES OF ACTION

COUNT I
PUBLIC NUISANCE
(Against all Defendants)

326. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

327. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable and substantial interference with a right common to the general public, which is the proximate cause of, and/or substantial factor leading to, Plaintiff's injury. *See* Restatement Second, Torts § 821B. *See also City of Portland v. Boeing Company*, 179 F. Supp. 2d 1190, 1195 (D. Or. 2001) ("Where a private party can establish that it has suffered an injury of a special character separate and distinct from that suffered by the general public, a claim for private recovery on a public nuisance will exist.").

328. The residents of Plaintiff's Community have a common right to be free from conduct that creates an unreasonable jeopardy to the public health, welfare and safety, and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

329. Defendants intentionally, unlawfully, and recklessly manufacture, market, distribute, and sell prescription opioids that Defendants know, or reasonably should know, will be diverted, causing widespread distribution of prescription opioids in and/or to Plaintiff's Community, resulting in addiction and abuse, an elevated level of crime, death and injuries to the residents of Plaintiff's Community, a higher level of fear, discomfort and inconvenience to the residents of Plaintiff's Community, and direct costs to Plaintiff.

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330. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used for non-medical purposes. Because of Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

331. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in the Plaintiff's Community. Defendants are in the business of manufacturing or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under federal and state law as substances posing a high potential for abuse and severe addiction. Defendants created an intentional nuisance. Defendants' actions created and expanded the abuse of opioids, drugs specifically codified as constituting severely harmful substances.

332. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Defendants' abdication of their gate-keeping and diversion prevention duties, and the Manufacturer Defendants' fraudulent marketing activities, have caused harm to the entire community that includes, but is not limited to the following:

a. The high rates of use leading to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.

b. Even children have fallen victim to the opioid epidemic. Easy access to prescription opioids made opioids a recreational drug of choice among teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

c. Even those residents of Plaintiff's Community who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gate-

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keeper duties and fraudulent promotions. Many residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

d. The opioid epidemic has increased health care costs.

e. Employers have lost the value of productive and healthy employees.

f. Defendants' conduct created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.

g. Defendants' dereliction of duties and/or fraudulent misinformation campaign pushing dangerous drugs resulted in a diverted supply of narcotics to sell, and the ensuing demand of addicts to buy them. More prescription opioids sold by Defendants led to more addiction, with many addicts turning from prescription opioids to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.

h. The diversion of opioids into the secondary, criminal market and the increased number of individuals who abuse or are addicted to opioids increased the demands on health care services and law enforcement.

i. The significant and unreasonable interference with the public rights caused by Defendants' conduct taxed the human, medical, public health, law enforcement, and financial resources of the Plaintiff's Community.

j. Defendants' interference with the comfortable enjoyment of life in the Plaintiff's Community is unreasonable because there is little social utility to prescribing opioid use for chronic pain and no social utility in opioid diversion and abuse, any potential value of either practice is outweighed by the gravity of the harm inflicted by Defendants' actions.

333. Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

334. Each Defendant has significantly and unreasonably interfered with and injuriously affected rights common to the general public, specifically including the rights of the people of the Plaintiff's Community to public health, public safety, public peace, public comfort, and public convenience. The public nuisance caused by Defendants' diversion of dangerous drugs has caused substantial annoyance, inconvenience, and injury to the public.

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335. Defendants' conduct in illegally distributing and selling prescription opioids, or causing such opioids to be distributed and sold, where Defendants know, or reasonably should know, such opioids will be diverted and possessed and/or used illegally in Plaintiff's Community is of a continuing nature, creating an ongoing nuisance.

336. Because of the continued use and addiction caused by these illegally-distributed opioids, the public will continue to fear for its health, safety and welfare, and will be subjected to conduct that creates a disturbance and reasonable apprehension of danger to person and property.

337. Defendants' intentional and unlawful actions and omissions and unreasonable interference with a right common to the public are of a continuing nature.

338. Defendants know, or reasonably should know, that their conduct causes an unreasonable invasion of the public right to health, safety and welfare and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

339. Stemming the flow of illegally distributed prescription opioids, and abating the nuisance caused by the illegal flow of opioids, will help to alleviate this problem, save lives, prevent injuries and make Plaintiff's Community a safer place to live.

340. The damages available to the Plaintiff include, *inter alia*, recoupment of governmental costs, flowing from an ongoing and persistent public nuisance which the government seeks to abate. Defendants' conduct is ongoing and persistent, and the Plaintiff seeks all damages flowing from Defendants' conduct. Plaintiff further seeks to abate the nuisance and harm created by Defendants' conduct.

341. As a direct result of Defendants' conduct, the Plaintiff and Plaintiff's Community have suffered actual injury and damages including, but not limited to, significant expenses for police, emergency, health, and other services. The Plaintiff here seeks recovery for its own harm.

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342. The Plaintiff and Plaintiff's Community have sustained specific and special injuries because its damages include, *inter alia*, health services, law enforcement expenditures, and costs related to opioid addiction treatment and overdose prevention.

343. The Plaintiff further seeks to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and interference with a right common to the public.

344. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent activity and fraudulent misrepresentations.

345. Plaintiff seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including *inter alia* injunctive relief, expenses to abate the nuisance, restitution, disgorgement of profits, compensatory damages, civil penalties and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

COUNT II

RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT
18 U.S.C. § 1961, *et seq.*
(Against Defendants Purdue, Cephalon, Janssen, and Endo)
(The "Opioid Marketing Enterprise")

346. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

347. Plaintiff brings this Claim against the following Defendants, as defined above: Purdue, Cephalon, Janssen, and Endo (referred to collectively for this Claim as the "RICO Marketing Defendants").

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348. At all relevant times, the RICO Marketing Defendants were and are "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

349. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. § 1962(c).

350. The term "enterprise" is defined as including "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4). The definition of "enterprise" in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section "describes two separate categories of associations that come within the purview of an 'enterprise' —the first encompassing organizations such as corporations, partnerships, and other 'legal entities,' and the second covering 'any union or group of individuals associated in fact although not a legal entity.'" *United State v. Turkette*, 452 U.S. 576, 577 (1981).

351. Beginning in the early 1990s, the RICO Marketing Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully increasing the volume of opioids they sold. The RICO Marketing Defendants knew that they could not increase their profits without misrepresenting that opioids were non-addictive and safe for the long-term treatment of chronic pain.

352. The generally-accepted standards of medical practice prior to the 1990s dictated that opioids should only be used in short durations to treat acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the evidence of addiction and lack of

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evidence indicating that opioids improved patients' ability to overcome pain and regain function, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

353. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the RICO Marketing Defendants formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain. The association-in-fact enterprise alleged in the previous and subsequent paragraphs is referred to as the "Opioid Marketing Enterprise."

354. The RICO Marketing Defendants formed an association-in-fact enterprise consisting of "advocacy groups and professional societies"—Front Groups—and paid "physicians affiliated with these groups"—KOLs—in order to unlawfully increase the demand for opioids. Through their personal relationships, the RICO Marketing Defendants and members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose. The RICO Marketing Defendants' substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.[177]

355. The RICO Marketing Defendants, through the Opioid Marketing Enterprise, made misleading statements and misrepresentations about opioids that downplayed the risk of addiction

[177] *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members' Office, February 12, 2018 https://www.hsdl.org/?abstract&did=808171 ("*Fueling an Epidemic*"), at 1.

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and exaggerated the benefits of opioid use, including: (1) downplaying the serious risk of addiction; (2) creating and promoting the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerating the effectiveness of screening tools to prevent addiction; (4) claiming that opioid dependence and withdrawal are easily managed; (5) denying the risks of higher opioid dosages; and (6) exaggerating the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction.

356. The RICO Marketing Defendants also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the RICO Marketing Defendants' claims.

357. The RICO Marketing Defendants' scheme, and the common purpose of the Opioid Marketing Enterprise, has been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.[178] In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[179]

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[178] *See* Katherine Eban, *OxyContin: Purdue Pharma's Painful Medicine*, Fortune, Nov. 9, 2011, http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/; David Crow, *Drugmakers Hooked on $10bn Opioid Habit*, Fin. Times, Aug. 10, 2016, https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95.

[179] Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), http://turnthetiderx.org/; *Fueling An Epidemic*, *supra* n.3, at 1.

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358. The scheme devised and implemented by the RICO Marketing Defendants amounted to a common course of conduct designed to ensure that the RICO Marketing Defendants unlawfully increased their sales and profits through misrepresentations about the addictive nature and effective use of the RICO Marketing Defendants' drugs. As Senator McCaskill aptly recognized:

> The opioid epidemic is the direct result of a calculated marketing and sales strategy developed in the 90's, which delivered three simple messages to physicians. First, that chronic pain was severely undertreated in the United States. Second, that opioids were the best tool to address that pain. And third, that opioids could treat pain without risk of serious addiction. As it turns out, these messages were exaggerations at best and outright lies at worst.[180]

A. THE OPIOID MARKETING ENTERPRISE

359. The Opioid Marketing Enterprise consists of the RICO Marketing Defendants, the Front Groups, and the KOLs – each of whom is identified below:

- **The RICO Marketing Defendants**
  - Purdue
  - Cephalon
  - Janssen
  - Endo
- **The Front Groups**
  - American Pain Foundation ("APF")
  - American Academy of Pain Medicine ("AAPM")
  - American Pain Society ("APS")
  - Federation of State Medical Boards ("FSMB")
  - U.S. Pain Foundation ("USPF")
  - American Geriatrics Society ("AGS")
- **The KOLs**
  - Dr. Russell Portenoy ("Dr. Portenoy")
  - Dr. Lynn Webster ("Dr. Webster")

[180] *See*, *LIVESTREAM: Insys Opioid Sales and Marketing Practices Roundtable*, September 12, 2017, at 31:03-31:37, https://www.youtube.com/watch?v=k9mrQa8_vAo (last visited Mar. 1, 2018).

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- Dr. Perry Fine ("Dr. Fine")
- Dr. Scott M. Fishman ("Dr. Fishman")

360. The Opioid Marketing Enterprise is an ongoing and continuing business organization that created and maintained systematic links, interpersonal relationships and engaged in a pattern of predicate acts (i.e., racketeering activity) in order to further the common purpose of the enterprise: unlawfully increasing profits and revenues from the continued prescription and use of opioids for long-term chronic pain. Each of the individuals and entities who formed the Opioid Marketing Enterprise is an entity or person within the meaning of 18 U.S.C. § 1961(3) and acted to enable the common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

361. In order to accomplish the common purpose, members of the Opioid Marketing Enterprise repeatedly and systematically misrepresented – affirmatively, and through half-truths and omissions – that opioids are non-addictive and safe for the effective treatment of long-term, chronic, non-acute and non-cancer pain, and for other off-label uses not approved by the FDA. The Opioid Marketing Enterprise misrepresented and concealed the serious risks and lack of corresponding benefits of using opioids for long-term chronic pain. By making these misrepresentations, the Opioid Marketing Enterprise ensured that a large number of opioid prescriptions would be written and filled for chronic pain.

362. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each RICO Marketing Defendant and its members; (b) was separate and distinct from the pattern of racketeering in which the RICO Marketing Defendants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the RICO Marketing Defendants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including

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between the RICO Marketing Defendants and each of the Front Groups and KOLs; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit.

363. The persons and entities engaged in the Opioid Marketing Enterprise are systematically linked through contractual relationships, financial ties, personal relationships, and continuing coordination of activities, as spearheaded by the RICO Marketing Defendants.

364. Each of the RICO Marketing Defendants, and each member of the Opioid Marketing Enterprise had systematic links to and personal relationships with each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. Each of the RICO Marketing Defendants coordinated their marketing efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry friendly and would work together with the RICO Marketing Defendants to advance the common purpose of the Opioid Marketing Enterprise.

1. The RICO Marketing Defendants

365. In addition to their systematic links to and personal relationships with the Front Groups and KOLS, described below, the RICO Marketing Defendants had systematic links to and personal relationships with each other through their participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities, including but not limited to, the Pain Care Forum and the Healthcare Distribution Alliance.

366. The Pain Care Forum has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. APF is credited with creating the PCF in 2004. Upon information and belief, PCF was created with the stated goal of offering a "setting where multiple organizations can share information" and "promote and support

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taking collaborative action regarding federal pain policy issues." Upon information and belief, past APF President Will Rowe described the PCF as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

367. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF, including the RICO Marketing Defendants, quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

368. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drugmakers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[181] Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[182]

369. Not surprisingly, each of the RICO Marketing Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.[183] In 2012, membership and participating organizations in the PCF included the HDA (of which all the RICO Marketing Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company for Janssen Pharmaceuticals), and Teva (the parent company of Cephalon).[184] Each of

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[181] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (last visited Sept. 19, 2017), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic (emphasis added).

[182] *Id*.

[183] PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf (last visited Mar. 8, 2018).

[184] *Id*. Upon information and belief, Mallinckrodt became an active member of the PCF sometime after 2012.

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the RICO Marketing Defendants worked together through the PCF to advance the interests of the Opioid Marketing Enterprise. But, the RICO Marketing Defendants were not alone; many of the RICO Marketing Defendants' Front Groups were also members of the PCF, including the American Academy of Pain Management, the American Pain Foundation, and the American Pain Society. Upon information and belief, the RICO Marketing Defendants' KOLs were also members of and participated in the PCF.

370. Through the Pain Care Forum, the RICO Marketing Defendants met regularly and in person to form and take action to further the common purpose of the Opioid Marketing Enterprise and shape the national response to the ongoing prescription opioid epidemic.

371. Through the had—or Healthcare Distribution Alliance—the RICO Marketing Defendants "strengthen[ed] . . . alliances"[185] and took actions to further the common purpose of the Opioid Marketing Enterprise.

372. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[186] Clearly, membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and "alliances" between the RICO Marketing Defendants.

373. The closed meetings of the HDA's councils, committees, task forces and working groups provided the RICO Marketing Defendants with the opportunity to work closely together,

[185] Manufacturer Membership Benefits, Healthcare Distribution Alliance, (last visited Sept. 14, 2017), https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en (emphasis added).

[186] *Id*.

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confidentially, to develop and further the common purpose and interests of the Opioid Marketing Enterprise.

374. The HDA also offered multiple conferences, including annual business and leadership conferences through which the RICO Marketing Defendants had an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[187] The HDA and its conferences were significant opportunities for the RICO Marketing Defendants to interact at the executive level and form and take actions in furtherance of the common purpose of the Opioid Marketing Enterprise. It is clear that the RICO Marketing Defendants embraced this opportunity by attending and sponsoring these events.[188]

375. The systematic contacts and personal relationships developed by the RICO Marketing Defendants through the PCF and the HDA furthered the common purpose of the Opioid Marketing Enterprise because it allowed the RICO Marketing Defendants to coordinate the conduct of the Opioid Marketing Enterprise by, including but not limited to, coordinating their interaction and development of relationships with the Front Groups and KOLs.

2. The Front Groups

376. Each of the RICO Marketing Defendants had systematic links to and personal relationships with Front Groups that operated as part of the Opioid Marketing Enterprise to further the common purpose of unlawfully increasing sales by misrepresenting the non-addictive and

[187] Business and Leadership Conference – Information for Manufacturers, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers (last visited Sept. 14, 2017).

[188] 2015 Distribution Management Conference and Expo, Healthcare Distribution Alliance, https://web.archive.org/web/20160119132611/http://www.healthcaredistribution.org:80/events/2016-distribution-management-conference/previous-attendees (last visited May 4, 2018).

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effective use of opioids for the treatment of long-term chronic pain. As recently reported by the U.S. Senate in "*Fueling an Epidemic*":

> The fact that these same manufacturers provided millions of dollars to the groups described below suggests, at the very least, a direct link between corporate donations and the advancement of opioids-friendly messaging. By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic.[189]

377. "Patient advocacy organizations and professional societies," like the Front Groups, "play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public."[190] "Even small organizations—with 'their large numbers and credibility with policymakers and the public'—have 'extensive influence in specific disease areas.' Larger organizations with extensive funding and outreach capabilities 'likely have a substantial effect on policies relevant to their industry sponsors.'"[191] Indeed, as reflected below, the U.S. Senate's report found that the RICO Marketing Defendants made nearly $9 million worth of contributions to various Front Groups, including members of the Opioid Marketing Enterprise.[192]

[189] Fueling an Epidemic, at p. 1.

[190] *Id*. at p. 2

[191] *Id*.

[192] *Id*. at p. 3.

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FIGURE 1: Manufacturer Payments to Selected Groups, 2012-2017

	Purdue[22]	Janssen[23]	Depomed	Insys	Mylan	Total
Academy of Integrative Pain Management	$1,091,024.86	$128,000.00	$43,491.95	$3,050.00[24]	$0.00	**$1,265,566.81**
American Academy of Pain Medicine	$725,584.95	$83,975.00	$332,100.00	$57,750.00	$0.00	**$1,199,409.95**
AAPM Foundation	$0.00	$0.00	$304,605.00	$0.00	$0.00	**$304,605.00**
ACS Cancer Action Network	$168,500.00[25]	$0.00	$0.00	$0.00	$0.00	**$168,500.00**
American Chronic Pain Association	$312,470.00	$50,000.00	$54,670.00	$0.00	$0.00	**$417,140.00**
American Geriatrics Society	$11,785.00[26]	$0.00	$0.00	$0.00	$0.00	**$11,785.00**
American Pain Foundation	$25,000.00	$0.00	$0.00	$0.00	$0.00	**$25,000.00**
American Pain Society	$542,259.52	$88,500.00	$288,750.00	$22,965.00	$20,250.00	**$962,724.52**
American Society of Pain Educators	$30,000.00	$0.00	$0.00	$0.00	$0.00	**$30,000.00**
American Society of Pain Management Nursing	$242,535.00	$55,177.85[27]	$25,500.00[28]	$0.00	$0.00	**$323,212.85**
The Center for Practical Bioethics	$145,095.00	$18,000.00	$0.00	$0.00	$0.00	**$163,095.00**
The National Pain Foundation[29]	$0.00	$0.00	$0.00	$562,500.00	$0.00	**$562,500.00**
U.S. Pain Foundation	$359,300.00	$41,500.00	$22,000.00	$2,500,000.00[30]	$0.00	**$2,922,800.00**
Washington Legal Foundation	$500,000.00	$0.00	$0.00	$0.00	$0.00	**$500,000.00**
	$4,153,554.33	**$465,152.85**	**$1,071,116.95**	**$3,146,265.00**	**$20,250.00**	**$8,856,339.13**

378. The Front Groups included in the Opioid Marketing Enterprise "have promoted messages and policies favorable to opioid use while receiving millions of dollars in payments from opioid manufacturers. Through criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often

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supported industry interests at the expense of their own constituencies.[193] And, as reflected below, many of the RICO Marketing Defendants' Front Groups received the largest contributions:[194]

FIGURE 5: Group Rankings by Manufacturer Payments, 2012-2017

U.S. Pain Foundation	$2,922,800.00
Academy of Integrative Pain Management	$1,265,566.81
American Academy of Pain Medicine	$1,199,409.95
American Pain Society	$962,724.52
The National Pain Foundation	$562,500.00
Washington Legal Foundation	$500,000.00
American Chronic Pain Association	$417,140.00
American Society of Pain Management Nursing	$323,212.85
AAPM Foundation	$304,605.00
ACS Cancer Action Network	$168,500.00
The Center for Practical Bioethics	$163,095.00
American Society of Pain Educators	$30,000.00
American Pain Foundation	$25,000.00
American Geriatrics Society	$11,785.00

379. But, the RICO Marketing Defendants connection with and control over the Front Groups did not end with financial contributions. Rather, the RICO Marketing Defendants made substantial contributions to physicians affiliated with the Front Groups totaling more than $1.6 million.[195] Moreover, the RICO Marketing Defendants "made substantial payments to individual group executives, staff members, board members, and advisory board members" affiliated with the Front Groups subject to the Senate Committee's study.[196]

[193] *Id*. at p. 3.

[194] *Id*. at p. 7.

[195] *Id*. at p. 3.

[196] *Id*. at p. 10.

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FIGURE 7: Purdue, Janssen, Insys, Depomed, and Mylan Payments to Groups and Group-Affiliated Individuals, 2012-Present[41]

	Payments to Group	Payments to Group-Affiliated Individuals	Total
U.S. Pain Foundation	$2,922,800.00	$126.20	$2,922,926.20
The National Pain Foundation	$562,500.00	$839,848.84	$1,402,348.84
Academy of Integrative Pain Management	$1,265,566.81	$30,223.42	$1,295,790.23
American Academy of Pain Medicine	$1,199,409.95	$16,462.42	$1,215,872.37
American Pain Society	$962,724.52	$95,474.56	$1,058,199.08
AAPM Foundation	$304,605.00	$314,175.58	$618,780.58
Washington Legal Foundation	$500,000.00	N/A	$500,000.00
American Chronic Pain Association	$417,140.00	$31,265.87	$448,405.87
American Society of Pain Management Nursing	$323,212.85	N/A	$323,212.85
American Society of Pain Educators	$30,000.00	$280,765.92	$310,765.92
The Center for Practical Bioethics	$163,095.00	$7,116.86	$170,211.86
ACS Cancer Action Network	$168,500.00	N/A	$168,500.00
American Pain Foundation	$25,000.00	N/A	$25,000.00
American Geriatrics Society	$11,785.00	$194.13	$11,979.13
Total	$8,856,339.13	$1,615,653.80	$10,471,992.93

380. As described in more detail below,[197] the RICO Marketing Defendants "amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain."[198] They also "lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding."[199]

[197] The activities that the Front Groups engaged in, and the misrepresentations that they made, in furtherance of the common purpose of the Opioid Marketing Enterprise are alleged more fully below, under the heading "Conduct of the Opioid Marketing Enterprise."

[198] *Id*. at 12-15.

[199] *Id*. at 12.

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381. The systematic contacts and interpersonal relationships of the RICO Marketing Defendants, and the Front Groups are further described below:

382. The American Pain Foundation ("APF") - The American Pain Foundation was the most prominent member of the RICO Marketing Defendants' Front Groups and was funded almost exclusively by the RICO Marketing Defendants. Upon information and belief, APF received more than $10 million in funding from the RICO Marketing Defendants between 2007 and the close of its business in May 2012. The APF had multiple contacts and personal relationships with the RICO Marketing Defendants through its many publishing and educational programs, funded and supported by the RICO Marketing Defendants.

383. Upon information and belief, representatives of the RICO Marketing Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

384. Furthermore, APF's Board of Directors was largely comprised of doctors who were on Defendants' payrolls, either as consultants or speakers at medical events.[200] As described below, many of the KOLs involved in the Opioid Marketing Enterprise also served in leadership positions within the APF.

385. In December 2011, a ProPublica investigation found that in 2010, nearly 90% of APF's funding came from the drug and medical device community, including RICO Marketing

[200] Charles Ornstein and Tracy Weber, *The Champion of Painkillers*, ProPublica (Dec. 23, 2011), https://www.propublica.org/article/the-champion-of-painkillers.

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Defendants.[201] More specifically, APF received approximately $2.3 million from industry sources out of total income of $2.85 million in 2009. It's budget for 2010 projected receipt of approximately $2.9 million from drug companies, out of total income of approximately $3.5 million. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's Board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[202]

386. The American Academy of Pain Medicine ("AAPM") – The AAPM was another Front Group that had systematic ties and personal relationships with the RICO Marketing Defendants.

387. The RICO Marketing Defendants internally viewed AAPM as "industry friendly," with RICO Marketing Defendants' advisors and speakers among its active members. The RICO Marketing Defendants attended AAPM conferences, funded its CMEs and satellite symposia, and distributed its publications. AAPM conferences heavily emphasized sessions on opioids. AAPM presidents have included top industry-supported KOLs like Perry Fine and Lynn Webster.

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[201] Charles Ornstein & Tracy Weber, *Patient advocacy group funded by success of painkiller drugs, probe finds*, Wash. Post (Dec. 23, 2011), https://www.washingtonpost.com/national/healthscience/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probefinds/2011/12/20/gIQAgvczDP_story. html?utm_term=. 22049984c606.

[202] Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies' Ties to Pain Groups*, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

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388. Upon information and belief, representatives of the RICO Marketing Defendants, often at informal meetings at conferences, suggested activities and publications for AAPM to pursue. AAPM then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

389. Upon information and belief, members of AAPM's Board of Directors were doctors who were on the RICO Marketing Defendants' payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs involved in the Opioid Marketing Enterprise also served in leadership positions within the AAPM.

390. The American Pain Society ("APS") – The APS was another Front Group with systematic connections and interpersonal relationships with the RICO Marketing Defendants. APS was one of the Front Groups investigated by Senators Grassley and Baucus, as evidenced by their May 8, 2012 letter arising out of their investigation of "extensive ties between companies that manufacture and market opioids and non-profit organizations" that "helped created a body of dubious information favoring opioids."[203]

391. Upon information and belief, representatives of the RICO Marketing Defendants, often at informal meetings at conferences, suggested activities and publications for APS to pursue. APS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

[203] Letter from U.S. Senators Charles E. Grassley and Max Baucus to Catherine Underwood, Executive Director American Pain Society, (May 8, 2012), https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American %20Pain%20Society.pdf.

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392. Upon information and belief, members of APS's Board of Directors were doctors who were on the RICO Marketing Defendants' payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs involved in the Opioid Marketing Enterprise also served in leadership positions within the APS.

393. The Federation of State Medical Boards ("FSMB") - FSMB was another Front Group with systematic connections and interpersonal relationships with the RICO Marketing Defendants. In addition to the contributions reported in *Fueling an Epidemic*, a June 8, 2012 letter submitted by FSMB to the Senate Finance Committee disclosed substantial payments from the RICO Marketing Defendants beginning in 1997 and continuing through 2012.[204] Not surprisingly, the FSMB was another one of the Front Groups investigated by Senators Grassley and Baucus, as evidenced by their May 8, 2012 letter arising out of their investigation of "extensive ties between companies that manufacture and market opioids and non-profit organizations" that "helped created a body of dubious information favoring opioids."[205]

394. The U.S. Pain Foundation ("USPF") – The USPF was another Front Group with systematic connections and interpersonal relationships with the RICO Marketing Defendants. The USPF was one of the largest recipients of contributions from the RICO Marketing Defendants, collecting nearly $3 million in payments between 2012 and 2015 alone.[206] The USPF was also a

[204] June 8, 2012 Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley.

[205] Letter from U.S. Senators Charles E. Grassley and Max Baucus to Catherine Underwood, Executive Director American Pain Society, (May 8, 2012), https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American %20Pain%20Society.pdf.

[206] Fueling an Epidemic, at p. 4.

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critical component of the Opioid Marketing Enterprise's lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertises its ties to the RICO Marketing Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (i.e., Janssen), and Mallinckrodt as "Platinum," "Gold," and "Basic" corporate members.[207] Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

395. American Geriatrics Society ("AGS") – The AGS was another Front Group with systematic connections and interpersonal relationships with the RICO Marketing Defendants. The AGS was a large recipient of contributions from the RICO Marketing Defendants, including Endo, Purdue and Janssen. AGS contracted with the RICO Marketing Defendants to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (The Management of Persistent Pain in Older Persons, hereinafter "2002 AGS Guidelines") and 2009 (Pharmacological Management of Persistent Pain in Older Persons,[208] hereinafter "2009 AGS Guidelines"). According to news reports, AGS has received at least $344,000 in funding from opioid manufacturers since 2009.[209] AGS's complicity in the common purpose of the Opioid Marketing Enterprise is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did

[207] *Id*. at 12; Transparency, U.S. Pain Foundation, https://uspainfoundation.org/transparency/ (last visited Mar. 9, 2018).

[208] *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331, 1339, 1342 (2009), available at https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf (last visited Mar. 9, 2018).

[209] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee J. Sentinel, May 30, 2012.

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not want to receive up-front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

396. Upon information and belief, representatives of the RICO Marketing Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

397. Upon information and belief, members of AGS Board of Directors were doctors who were on the RICO Marketing Defendants' payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs involved in the Opioid Marketing Enterprise also served in leadership positions within the AGS.

398. There was regular communication between each of the RICO Marketing Defendants, Front Groups and KOLs, in which information was shared, misrepresentations were coordinated, and payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the use of interstate wires and mail in which the RICO Markets Defendants, Front Groups, and KOLs share information necessary to overcome objections and resistance to the use of opioids for chronic pain. The RICO Marketing Defendants, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed to take actions to hide the scheme and continue its existence.

399. At all relevant times, the Front Groups were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups

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were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiff. But for the Opioid Marketing Enterprise's unlawful fraud, the Front Groups would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

3. The KOLs

400. Similarly, each of the RICO Marketing Defendants financed, supported, utilized and relied on the same KOLs by paying, financing, supporting, managing, directing, or overseeing, and/or relying on their work. Upon Information and belief, the RICO Marketing Defendants cultivated this small circle of doctors solely because they favored the aggressive treatment of chronic pain with opioids.

401. The RICO Marketing Defendants and the Opioid Marketing Enterprise relied on their KOLs to serve as part of their speakers' bureaus and to attend programs with speaker's bureaus. The RICO Marketing Defendants graded their KOLs on performance, post-program sales, and product usage. Furthermore, the RICO Marketing Defendants expected their KOLs to stay "on message," and obtained agreements from them, in writing, that "all slides must be presented in their entirety and without alterations . . . and in sequence."

402. The RICO Marketing Defendants' KOLs have been at the center of the Opioid Marketing Enterprise's marketing efforts, presenting the false appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. As described in more detail below, the KOLs have written, consulted, edited, and lent their names to books and articles, and given speeches, and CMEs supporting chronic opioid therapy. They have served on

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committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain (even while acknowledging the lack of evidence in support of that position) and on the boards of the pro-opioid Front Groups identified above.

403. The RICO Marketing Defendants and KOLs all had systematic connections and interpersonal relationships, as described below, through the KOLs receipt of payments from the RICO Marketing Defendants and Front Groups, the KOLs' authoring, publishing, speaking, and educating on behalf of the RICO Marketing Defendants, and their leadership roles and participation in the activities of the Front Groups, which were in turn financed by the RICO Marketing Defendants.

404. The systematic contacts and interpersonal relationships of the KOLs with the RICO Marketing Defendants and Front Groups are described below:

405. Dr. Russell Portenoy – Dr. Portenoy was one of the main KOLs whom the RICO Marketing Defendants identified and promoted to further the common purpose of the Opioid Marketing Enterprise. Dr. Portenoy is credited as one of the authors on a primary pillar of the RICO Marketing Defendants' misrepresentation regarding the risks and benefits of opioid use.[210]

[210] In 1986, the medical journal Pain, which would eventually become the official journal of the American Pain Society ("APS"), published an article by Portenoy and Foley summarizing the results of a "study" of 38 chronic non-cancer pain patients who had been treated with opioid painkillers. Portenoy and Foley concluded that, for non-cancer pain, opioids "can be safely and effectively prescribed to selected patients with relatively little risk of producing the maladaptive behaviors which define opioid abuse." However, their study was neither scientific nor did it meet the rigorous standards commonly used to evaluate the validity and strength of such studies in the medical community. For instance, there was no placebo control group, and the results were retroactive (asking patients to describe prior experiences with opioid treatment rather than less biased, in-the-moment reports). The authors themselves advised caution, stating that the drugs should be used as an "alternative therapy" and recognizing that longer term studies of patients on opioids would have to be performed. None were. See Russell K. Portenoy & Kathleen M. Foley,

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Dr. Portenoy had financial relationships with at least a dozen pharmaceutical companies, most of which produced prescription opioids.[211]

406. Dr. Portenoy, published, spoke, consulted, appeared in advertisements and on television broadcasts, and traveled the country to travel the country to promote more liberal prescribing for many types of pain and conduct continuing medical education ("CME") seminars sponsored by the RICO Marketing Defendants and Front Groups.

407. Dr. Portenoy was also a critical component of the RICO Marketing Defendants' control over their Front Groups, and the Front Groups support of the Opioid Marketing Enterprise's common purpose. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.

408. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Dr. Portenoy admitted that his earlier work relied on evidence that was not "real" and left real evidence behind, all in furtherance of the Opioid Marketing Enterprise's common purpose:

> I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, none of which represented real evidence, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.[212]

Chronic use of opioid analgesics in non-malignant pain: report of 38 cases, 25(2) Pain 171-86 (May 1986).

[211] Anna Lembke, *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop*, (Johns Hopkins University Press 2016), at 59 (citing Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* (St. Martin's Press, 1st Ed 2003).

[212] Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube, 2:07-2:51, (Oct. 30, 2011), https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be.

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409. Dr. Lynn Webster – Dr. Webster was a critical component of the Opioid Marketing Enterprise, including advocating the RICO Marketing Defendants' fraudulent messages regarding prescription opioids and had systematic contacts and personal relationships with the RICO Marketing Defendants and the Front Groups.

410. Dr. Webster was the co-founder and Chief Medical Director of an otherwise unknown pain clinic in Salt Lake City, Utah (Lifetree Clinical Research), who went on to become one of the RICO Marketing Defendants' main KOLs. Dr. Webster was the President of American Academy of Pain Medicine ("AAPM") in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from the RICO Marketing Defendants (including nearly $2 million from Cephalon alone).

411. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than twenty of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

412. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and, for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue.

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413. Dr. Webster is also credited as one of the leading proponents of "pseudoaddiction" that the RICO Marketing Defendants, Front Groups and KOLs disseminated as part of the common purpose of the Opioid Marketing Enterprise.

414. Upon information and belief, in exchange for the payments he received from the RICO Marketing Defendants, Dr. Webster published, spoke, consulted, appeared in advertisements and on television broadcasts, and traveled the country to promote more liberal prescribing of opioids for many types of pain and conduct CME seminars sponsored by the RICO Marketing Defendants and Front Groups.

415. Like Dr. Portenoy, Dr. Webster later reversed his opinion and disavowed his previous work on and opinions regarding pseudoaddiction. Specifically, Dr. Webster acknowledged that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[213]

416. Dr. Perry Fine – Dr. Fine was a critical component of the Opioid Marketing Enterprise, including advocating the RICO Marketing Defendants' fraudulent messages regarding prescription opioids and had systematic contacts and personal relationships with the RICO Marketing Defendants and the Front Groups.

417. Dr. Fine was originally a doctor practicing in Utah, who received support from the RICO Marketing Defendants, including Janssen, Cephalon, Endo, and Purdue. Dr. Fine's ties to the RICO Marketing Defendants have been well documented.[214] He has authored articles and

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[213] John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html.

[214] Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 2:14 PM), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry.

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testified in court cases and before state and federal committees, and he served as president of the AAPM, and argued against legislation restricting high-dose opioid prescription for non-cancer patients. Multiple videos featured Fine delivering educational talks about prescription opioids. He even testified in a trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death.[215] He has also acknowledged having failed to disclose numerous conflicts of interest.

418. Dr. Fine was also a critical component of the RICO Marketing Defendants' control over their Front Groups, and the Front Groups support of the Opioid Marketing Enterprise's common purpose. Specifically, Dr. Fine served on the Board of Directors of APF and served as the President of the AAPM in 2011.

419. Upon information and belief, in exchange for the payments he received from the RICO Marketing Defendants, Dr. Fine published, spoke, consulted, appeared in advertisements and on television broadcasts, and he traveled the country to promote more liberal prescribing of opioids for many types of pain and to conduct CME seminars sponsored by the RICO Marketing Defendants and Front Groups.

420. Dr. Scott M. Fishman – Dr. Fishman was a critical component of the Opioid Marketing Enterprise, including advocating the RICO Marketing Defendants' fraudulent messages regarding prescription opioids and had systematic contacts and personal relationships with the RICO Marketing Defendants and the Front Groups.

[215] Linda Deutsch, *Doctor: 1,500 pills don't prove Smith was addicted*, Seattle Times (Sept. 22, 2010, 5:16 PM), http://www.seattletimes.com/entertainment/doctor-1500-pills-dont-prove-smith-was-addicted/.

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421. Although Dr. Fishman did not receive direct financial payments from the RICO Marketing Defendants, his ties to the opioid drug industry are legion.[216]

422. As Dr. Fishman's personal biography indicates, he is critical component of the RICO Marketing Defendants' control over their Front Groups, and the Front Groups support of the Opioid Marketing Enterprise's common purpose. Specifically, Dr. Fishman is an "internationally recognized expert on pain and pain management" who has served in "numerous leadership roles with the goal to alleviate pain."[217] Dr. Fishman's roles in the pain industry include "past president of the American Academy of Pain Medicine [AAPM], past chairman of the board of directors of the American Pain Foundation [APF], and past board member for the American Pain Society [APS]."[218] Dr. Fishman is also "the immediate past chair and a current member of the Pain Care Coalition of the American Society of Anesthesiologists, American Pain Society and Academy of Pain Medicine."[219] Dr. Fishman's leadership positions within the central core of the RICO Marketing Defendants' Front Groups was a direct result of his participation in the Opioid Marketing Enterprise and agreement to cooperate with the RICO Marketing Defendants' pattern of racketeering activity.

423. Upon information and belief, in exchange for the payments he received from the RICO Marketing Defendants, Dr. Fishman published, spoke, consulted, appeared in advertisements and on television broadcasts, and traveled the country to promote more liberal

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[216] Scott M. Fishman, M.D., Professor, U.C. Davis Health, Center for Advancing Pain Relief, https://www.ucdmc.ucdavis.edu/advancingpainrelief/our_team/Scott_Fishman.html (last visited Feb. 28, 2018).

[217] *Id.*

[218] *Id.*

[219] *Id.*

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prescribing of opioids for many types of pain and to conduct CME seminars sponsored by the RICO Marketing Defendants and Front Groups.

424. At all relevant times, the KOLs were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. The RICO Marketing Defendants' support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the RICO Marketing Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLS and Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and Plaintiff. But for the Opioid Marketing Enterprise's unlawful conduct, the KOLs would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs furthered the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

425. As public scrutiny and media coverage focused on how opioids ravaged communities in Oregon and throughout the United States, the Front Groups and KOLS did not challenge the RICO Marketing Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence.

426. The RICO Marketing Defendants, Front Groups and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Marketing Enterprise. As reported in *Fueling an Epidemic*, the Opioid Marketing Enterprise's conduct in

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furtherance of the common purpose of the Opioid Marketing Enterprise involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain; (2) lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or undermine CDC guidelines; and (4) efforts to limit prescriber accountability. The misrepresentations made in these publications are described in the following section.

427. Efforts to Minimize the Risk of Addiction and Promote Opioid Use As Safe for Long-Term Treatment of Chronic Pain – Members of the Opioid Marketing Enterprise furthered the common purpose of the enterprise by publishing and disseminating statements that minimized the risk of addiction and misrepresented the safety of using prescription opioids for long-term treatment of chronic, non-acute, and non-cancer pain. The misrepresentations made by the Opioid Marketing Enterprise and the RICO Marketing Defendants included the following:[220]

- *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997). The "landmark consensus" was published by the AAPM and APS. Dr. Portenoy was the sole consultant. A member of Purdue's speaker bureau authored the consensus.

- *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (1998, 2004, 2007).[221] These guidelines, originally published by the FSMB in collaboration with RICO Marketing Defendants, advocated that opioids were "essential" and that "misunderstanding of addiction" contributed to undertreated pain.

[220] These allegations are in addition to those pled earlier in the Complaint. RICO Marketing Defendants and the Opioid Marketing Enterprise began in 1997 and has continued unabated since that time. Therefore, this list is alleged as fully and completely as possible.

[221] *Model Policy for the Use of Controlled Substances for the Treatment of Pain*, Federation of State Medical Boards of the United States, May 2004, https://www.ihs.gov/painmanagement/includes/themes/newihstheme/display_objects/documents/modelpolicytreatmentpain.pdf (last visited Mar. 9, 2018).

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- *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions,* Testimony by John D. Giglio, M.A., J.D., Executive Direction of the APF (2002.)[222]

- *The Management of Persistent Pain in Older Persons* (2002). These guidelines were published by AGS with substantial funding from Endo, Purdue and Janssen.

- *Overview of Management Options* (2003, 2007, 2010, and 2013).[223] This CME was edited by Dr. Portenoy, sponsored by Purdue, and published by the American Medical Association. It taught that opioids, unlike non-prescription pain medication are safe at high doses. It also taught NSAIDs and other drugs, but not opioids, are unsafe at high doses.

- *Understanding Your Pain: Taking Oral Opioid Analgesic*s (2004).[224] This article, published by Endo Pharmaceuticals advocated that withdrawal and needing to take higher dosages are not signs of addiction.

- Interview by Paula Moyer with Scott M. Fishman, M.D. (2005). Dr. Fishman advocated that "the risks of addiction are . . . small and can be managed."[225]

- *Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: interim safety and tolerability results* (2006).[226] Dr. Webster gave this

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[222] *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions,* Testimony by John D. Giglio, M.A., J.D., Executive Direction of the APF (2002.)

[223] Portenoy, et al., *Overview of Management Options*, https://cme.ama-assn.org/activity/1296783/detail.aspx. Upon information and belief, this CME was published by the American Medical Association in 2003, 2007, 2010, and 2013.

[224] Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesic*s, Endo Pharmaceuticals (2004), https://www.yumpu.com/en/document/view/35479278/understanding-your-pain-taking-oral-opioid-analgesics (last visited Mar. 8, 2018).

[225] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005),

available at http://www.medscape.org/viewarticle/500829.

[226] Hale ME, Webster LR, Peppin JF, Messina J. *Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: interim safety and tolerability results. Program and abstracts of the annual meeting of the American Academy of Pain Medicine*; February 22-25, 2006; San Diego, California. Abstract 120. Published with permission of Lynn R. Webster, MD, https://www.medscape.org/viewarticle/524538_2 (last visited Mar. 6, 2018).

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CME, sponsored by Cephalon, that misrepresented that opioids were safe for the treatment of non-cancer pain.

- *Treatment Options: A Guide for People Living With Pain* (2007). This document was published by the APF and sponsored by Cephalon and Purdue.[227]

- *Responsible Opioid Prescribing: A Physician's Guide* (2007).[228] This book, authored by Dr. Fishman was financed by the FSMB with funding from Cephalon, Endo and Purdue.

- *Avoiding Opioid Abuse While Managing Pain* (2007).[229] This book, co-authored by Dr. Webster., misrepresented that for prescribers facing signs of aberrant behavior, increasing the dose in "most cases . . . should be a clinician's first response."

- *Screener and Opioid Assessment for Patients with Pain (SOAPP)® Version 1.0-SF* (2008).[230] This screening tool was published by the National Institutes of Health with support from Endo through an educational grant, and advocated that most patients are able to successfully remain on long-term opioid therapy without significant problems.

- *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (2007).[231] This article, sponsored by Endo, misrepresented that opioids are a highly effective class of analgesic drugs.

- *Opioid-Based Management of Persistent and Breakthrough Pain* (2008).[232] This document was written by Dr. Fine and sponsored by an educational grant from Cephalon. Dr. Fine advocated for the prescription of rapid onset opioids "in patients with non-cancer pain."

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[227] APF, *Treatment Options*, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

[228] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*, 8-9 (2007).

[229] Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain*, 59 (2007).

[230] *Screener and Opioid Assessment for Patients with Pain (SOAPP)® Version 1.0-SF*, PainEdu.org, 2008, https://www.nhms.org/sites/default/files/Pdfs/SOAPP-5.pdf (last visited Mar. 8, 2018).

[231] Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, https://www.painmedicinenews.com/download/BtoB_Opana_WM.pdf (last visited Mar. 8, 2018).

[232] Perry G Fine, MD, et al. *Opioid-Based Management of Persistent and Breakthrough Pain*, Pain Medicine News, https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain (last visited Feb. 27, 2018).

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- *Optimizing Opioid Treatment for Breakthrough Pain* (2008).[233] Dr. Webster presented an online seminar (webinar) sponsored by Cephalon, that misrepresented that non-opioid analgesics and combination opioids containing non-opioids are less effective because of dose limitations.

- *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain* (2009).[234] These guidelines were published by AAPM and APS. Fourteen of the twenty-one panel members, including Dr. Portenoy and Dr. Fine, received support from the RICO Marketing Defendants.

- *Pharmacological Management of Persistent Pain in Older Persons* (2009).[235] These guidelines were published by AGS, with substantial funding from Endo, Purdue, and Janssen, updated the 2002 guidelines and misrepresented that the risks of addiction are exceedingly low.

- *Iraq War Veteran Amputee, Pain Advocate and New Author Release Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families*,[236] American Pain Foundation, 2009. This article was published in 2009 and sponsored by Purdue.

- Good Morning America (2010). Dr. Portenoy appeared on Good Morning America and stated that "Addiction, when treating pain, is distinctly uncommon."[237]

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[233] Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, Medscape, http://www.medscape.org/viewarticle/563417_6 (last visited Dec. 11, 2017).

[234] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

[235] *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331, 1339, 1342 (2009), available at https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf (last visited Mar. 9, 2018).

[236] *Iraq War Veteran Amputee, Pain Advocate and New Author Release Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families*, Coalition for Iraq + Afghanistan Veterans, http://web.archive.org/web/20100308224011/http://coalitionforveterans.org:80/2009/10/iraq-war-veteran-amputee-pain-advocate-and-new-author-releases-exit-wounds-a-survival-guide-to-pain-management-for-returning-veterans-and-their-families (last visited Mar. 1, 2018)

[237] Good Morning America, (ABC television broadcast (Aug. 30, 2010).

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- *Finding Relief: Pain Management for Older Adults*, (2009).[238] This article was a collaboration between the American Geriatrics Society, AAPM and Janssen.

- *A Policymaker's Guide to Understanding Pain & Its Management, American Pain Foundation* (2011).[239] APF published this document, that was sponsored by Purdue, which argued that the notion of strong pain medication leading to addiction is a common misconception.

- *Managing Patient's Opioid Use: Balancing the Need and the Risk* (2011).[240] Dr. Webster presented a webinar, sponsored by Purdue, that misrepresented the ability to use risk screen tools, urine samples and patient agreements to prevent overuse and overdose death.

- *Safe and Effective Opioid Rotation* (2012).[241] This CME, delivered by Dr. Fine, that is also available online, advocated for the safe and non-addictive use of opioids to treat cancer and non-cancer patients over a person's "lifetime."

- *Pain: Opioid Facts* (2012).[242] This document was published online on Endo's website painknowledge.org and advocated for the use of opioids and downplayed the risk of addiction, even for people with a history of addiction and opioid use, and supported the concept of pseudoaddiction.

428. Efforts to Criticize or Undermine CDC Guidelines – Members of the Opioid Marketing Enterprise criticized or undermined the CDC Guidelines which represented "an important step – and perhaps the first major step from the federal government – toward limiting

[238] *Finding Relief, Pain Management for Older Adults*, (2009).

[239] *A Policymaker's Guide to Understanding Pain & Its Management*, American Pain Foundation (2011) at 5, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last visited Mar. 6, 2018).

[240] *See*, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, Emerging Solutions in Pain http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

[241] Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

[242] *Pain: Opioid Facts*, http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patiented/pdf/Patient%20Education%20b380_b385%20%20pf%20opiod.pdf (last visited Mar. 6, 2018).

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opioid prescriptions for chronic pain." The following are examples of the actions taken by Opioid Marketing Enterprise members to prevent restriction on over-prescription:

- Several Front Groups, including the U.S. Pain Foundation, and the AAPM criticized the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliations, and conflicts of interest of the individuals who participated in the construction of these guidelines."[243]

- The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating "that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence."[244]

429. In each of the actions performed by members of the Opioid Marketing Enterprise, described above, the members of the Opioid Marketing Enterprise made branded and unbranded marketing claims about prescription opioids that misrepresented prescription opioids as non-addictive and safe for use as identified in the following section.

4. Members of the Opioid Marketing Enterprise Furthered the Common Purpose by Making Misrepresentations.

430. The RICO Marketing Defendants, Front Groups and KOLs participated in the conduct of the Opioid Marketing Enterprise and shared in the common purpose of marketing opioids for chronic pain through a pattern of racketeering activity (including multiple instances of mail and wire fraud) by knowingly making material misrepresentations or omissions to Oregon prescribers, consumers, the general public, regulators and Plaintiff. All of the misrepresentations

[243] Pat Anson, *Chronic Pain Group Blasts CDC for Opioid Guidelines*, Pain News Networks, https://www.painnewsnetwork.org/stories/2015/9/22/chronic-pain-groups-blast-cdc-for-opioid-guidelines (last visited Mar. 8, 2018).

[244] Practical Pain Management, Responses and Criticisms Over New CDC Opioid Prescribing Guidelines, https://www.practicalpainmanagement.com/resources/news-and-research/responses-criticisms-over-new-cdc-opioid-prescribing-guidelines (last visited Sept. 28, 2017).

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made by members of the Opioid Marketing Enterprise furthered the common purpose of the Enterprise.

431. Members of the Opioid Marketing Enterprise, including the RICO Marketing Defendants, Front Groups and KOLs made multiple unbranded marketing misrepresentations about the benefits and risks of opioid use, in furtherance of the Opioid Marketing Enterprise's common purpose, as follows:

432. Members of the Opioid Marketing Enterprise minimized the risks of addiction and/or construed opioids as non-addictive:

- AAMP and APS endorsed the use of opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low.[245]
- "[O]pioids are safe and effective, and only in rare cases lead to addiction."[246]
- "[T]he risks of addiction are . . . small and can be managed."[247]

[245] *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997).

[246] *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions,* 107th Cong. 2 (Feb. 12, 2002) (testimony of John D. Giglio, M.A., J.D., Executive Director, American Pain Foundation), https://www.help.senate.gov/imo/media/doc/Giglio.pdf.

[247] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at http://www.medscape.org/viewarticle/500829.

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Medscape: Controversy surrounds both the undertreatment and overtreatment of pain. Overtreatment of pain obviously involves the fear of causing or perpetuating opioid drug dependency. What recommendations can you give to primary care physicians who are reluctant to prescribe opioids, either as adjuncts or primary agents for pain control, because of these fears?

Dr. Fishman: It used to be that when you had a patient with pain and you were worried about giving him or her a drug that may be abusable or may cause addiction, the safest thing to do was nothing, as though doing nothing would have no risks in and of itself. We know that the risks of addiction are there, but they are small and can be managed. The AAPM is going to be at the forefront, educating

- Calling opioids "'narcotics' reinforces myths and misunderstandings as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines."[248]

OPIOID ANALGESICS (NARCOTICS)
Opioid analgesics are another important class of medications that are very effective pain relievers. As mentioned before, they may also be called "narcotics." Unfortunately, this term is used by law enforcement to refer to drugs that are abused. Cocaine and heroin are called narcotics even though they are very different kinds of drugs. Calling opioid analgesics "narcotics" reinforces myths and misunderstandings as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines. In the pain treatment world, the word opioid is used when speaking about this class of medications.

- The risk of addiction is manageable for patients regardless of past abuse histories.[249]

- "[T]he likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low."[250]

- Patients might experience withdrawal symptoms associated with physical dependence as the decrease their dose, "[b]ut unlike actual addicts, such individuals, if they resume their opioid use, will only take enough medication to alleviate their pain."[251]

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[248] APF, *Treatment Options*, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

[249] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

[250] Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

[251] Brief Amici Curiae of American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio Pain Initiative, in Support of Defendants/Appellants, *Howland v. Purdue Pharma, L.P., et al.*, Appeal No. CA 2002 09 0220 (Butler Co., Ohio 12th Court of Appeals, Dec. 23, 2002) [hereinafter, *Howland* American Pain Foundation Amicus Brief],

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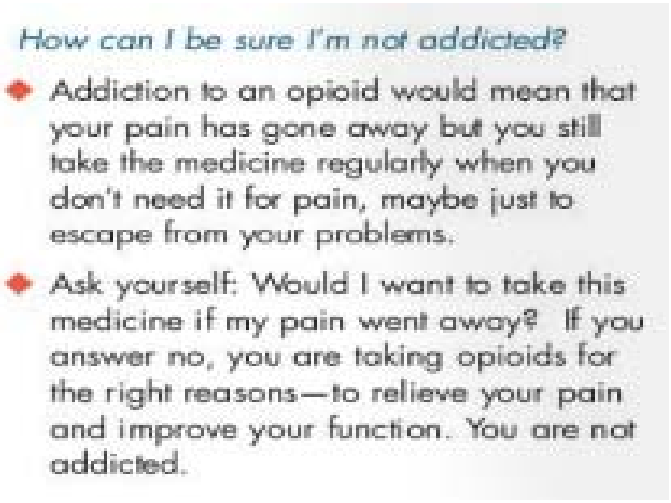
- "Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape your problems."[252]



How can I be sure I'm not addicted?

- Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problems.
- Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons—to relieve your pain and improve your function. You are not addicted.

- Even for patients assessed to have a risk of abuse, "it does not mean that opioid use will become problematic or that opioids are contraindicated." [253]

- "[P]eople who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted."[254]

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https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014-howland-apf-amicus.pdf.

[252] Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesic*s, Endo Pharmaceuticals (2004), https://www.yumpu.com/en/document/view/35479278/understanding-your-pain-taking-oral-opioid-analgesics (last visited Mar. 8, 2018).

[253] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*, 8-9 (2007).

[254] *Pain: Opioid Facts*, http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patiented/pdf/Patient%20Education%20b380_b385%20%20pf%20opiod.pdf (last visited Mar. 6, 2018).

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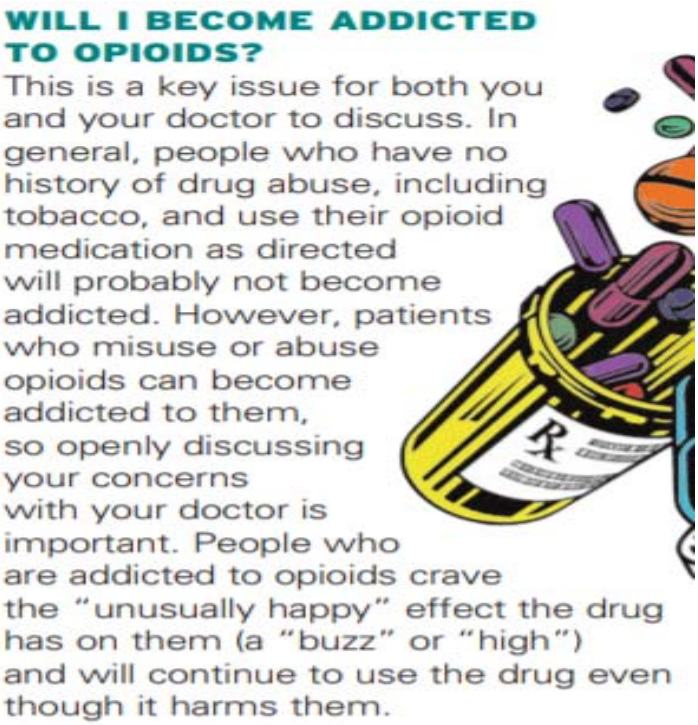
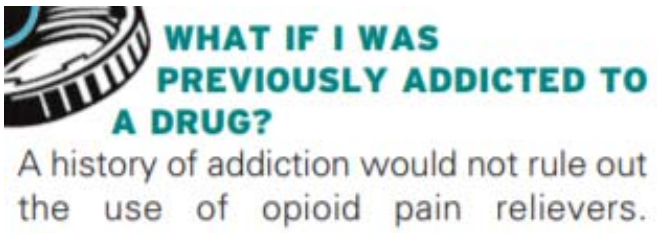


- "A history of addiction would not rule out the use of opioid pain relievers."[255]



- Purdue sponsored and Janssen and Endo provided grants for APF's *Exit Wounds* (2009), wherein they represented that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests it is so low as not to be a worry. *Exit Wounds* also taught veterans that opioid medications "increase your level of functioning." And it omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder. In fact, Janssen's label for Duragesic, states that use with benzodiazepines "may cause respiratory depression, [low blood pressure], and profound sedation or potentially

[255] *Id.*

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result in coma. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids. [256]

Iraq War Veteran Amputee, Pain Advocate and New Author Releases Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families

"Its now four years since I lay in the dirt, near death, on the side of the road in Fallujah. I'm grateful for all the things I have, and proud of all I've accomplished. In the end though, I don't measure how far I've come by goals achieved, or academic degrees earned, or running trophies won. For me, what counts is that pain no longer rules my life." – Derek McGinnis

The American Pain Foundation (APF) announces the release of Iraq War Veteran and Pain Advocate Derek McGinnis' first book, *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families*. Written in collaboration with nationally renowned pain experts, the release date of September 21 for Exit Wounds coincided with September's designation as Pain Awareness Month.

- Patients rarely become addicted to prescribed opioids.[257]

- Concern about patients becoming addicted reflects widespread failure to appreciate the distinction between "(1) *tolerance* – the body's tendency to become accustomed to a substance so that, over time, a larger amount is needed to produce the same physical effect (pain relief) and *physical dependence* – the state defined by the experience of adverse symptoms if a drug is abruptly withdrawn . . . each of which is common with pain patients . . . and, on the other hand, (2) the psychological and behavioral patterns – an unhealthy craving for, compulsive use of, and unhealthy fixation – that characterize *addiction*."[258]

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[256] *Iraq War Veteran Amputee, Pain Advocate and New Author Release Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families*, Coalition for Iraq + Afghanistan Veterans, http://web.archive.org/web/20100308224011/http://coalitionforveterans.org:80/2009/10/iraq-war-veteran-amputee-pain-advocate-and-new-author-releases-exit-wounds-a-survival-guide-to-pain-management-for-returning-veterans-and-their-families (last visited Mar. 1, 2018).

[257] Brief of Amici the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain, 2005 WL 2405247, *9 *United States v. Hurowitz*, 459 F.3d 463 (4th Cir. 2006) (citing Portenoy, Russell, et al., *Acute and Chronic Pain, in COMPREHENSIVE TEXTBOOK OF SUBSTANCE ABUSE*, 863-903 (Lowinson et al. eds., 4th ed. 2005); Portenoy et. al, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, PAIN, Vol. 25, 171-186, (1986)).

[258] Brief of Amici Russel K. Portenoy, *et al*., 2005 WL 2405249, *United States v. Hurowitz*, 459 F.3d 463 (4th Cir. 2006) (emphasis in original).

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- Evidence establishes that the risk of drug addiction (historically the principal *medical* justification for withholding or limiting opioids) is far *less* substantial than long and widely assumed.[259]

- Janssen, Endo, and Purdue contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. The "risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[260] None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids and the claim is, in fact, untrue. The study supporting this assertion does not analyze addiction rates by age and, as already noted, addiction remains a significant risk for elderly patients. Upon information and belief, Janssen, Purdue and Endo were aware of the AGS guidelines' content when each agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion.

> the addiction. Although the risks are exceedingly low in older patients with no current or past history of substance abuse, it is impossible to identify every patient who will abuse or divert prescribed opioids.[117] Therefore, many clinicians have adopted a Universal Precautions approach to pain management.[118] This paradigm stresses that every pa-

433. Members of the Opioid Marketing Enterprise advocated that opioids were safe and effective for long-term treatment of chronic, non-acute and non-cancer pain:

- "Opioids are an essential option for treating *moderate* to severe pain associated with surgery or trauma. They may also be an important part of the management of persistent pain unrelated to cancer."[261]

> ***Clinical uses***
> Opioids are an essential option for treating moderate to severe pain associated with surgery or trauma, and for pain related to cancer. They may also be an important part of the management of persistent pain unrelated to cancer. These medicines block pain

[259] *Id*. and sources cited at note 9.

[260] *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331, 1339, 1342 (2009), available at https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf (last visited Mar. 9, 2018).

[261] APF, *Treatment Options* (emphasis added), https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

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- Opioids were a safe and effective treatment of pain as part of a physicians' treatment guidelines.[262]

- The "small risk of abuse does not justify the withholding of these highly effective analgesics from chronic pain patients."[263]

- Opioids, unlike some non-prescription pain medications, are safe at high doses.[264]

- Falsely representing "recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems."[265]

- Opioid therapy is an appropriate treatment for chronic, non-cancer pain and integral to good medical practice.[266]

- Even for patients assessed to have a risk of abuse, "it does not mean that opioid use will become problematic or that opioids are contraindicated."[267]

- Broadly classifying pain syndromes as "either cancer- or non-cancer-related has limited utility," and recommended dispensing rapid onset opioids "in patients with non-cancer pain."[268]

- Opioids are safe and well-tolerated in patients with chronic pain and break through pain.[269]

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[262] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

[263] *Howland* American Pain Foundation Amicus Brief.

[264] Portenoy, et al., *Overview of Management Options*, https://cme.ama-assn.org/activity/1296783/detail.aspx. On information and belief, this CME was published in 2003, 2007, 2010, and 2013.

[265] *Screener and Opioid Assessment for Patients with Pain (SOAPP)® Version 1.0-SF*, PainEdu.org, 2008, https://www.nhms.org/sites/default/files/Pdfs/SOAPP-5.pdf (last accessed on March 8, 2018).

[266] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*, 8-9 (2007).

[267] *Id*.

[268] Perry G Fine, MD, et al. *Opioid-Based Management of Persistent and Breakthrough Pain*, Pain Medicine News, https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain (last visited Feb. 27, 2018).

[269] Hale ME, Webster LR, Peppin JF, Messina J. *Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: interim safety and tolerability results. Program and abstracts of the annual meeting of the American Academy of Pain Medicine*; February 22-25, 2006; San Diego, California. Abstract 120. Published with permission

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> The data suggest that FEBT is safe and well tolerated in opioid-tolerant patients with chronic noncancer pain. There was no respiratory depression, and a low incidence of treatment-related adverse events was reported. Thirty-five patients (37%) reported having at least 1 adverse event, the most common of which were nausea (7%) and dizziness (5%).

- Non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective than opioids because of dose limitations on non-opioids.[270]

> adverse events. Furthermore, although nonopioid analgesics, such as acetaminophen and NSAIDs/COX-2 inhibitors, are effective for nociceptive pain, their use in BTP is likewise restricted by dose-limiting toxicities, an onset of action that is delayed by 30 minutes or more, a long duration of action that could augment sedation and other side effects of the agent used for the baseline pain, and fears about renal and cardiovascular complications. Agents that combine an SAO, such as hydrocodone plus acetaminophen, aspirin, or ibuprofen, also are limited by potential adverse events and ceiling effects from the nonopioid component.

- Opioids can safely alleviate chronic pain unresponsive to other medication.[271]
- Medical organization and government-sponsored clinical guidelines support and encourage opioid treatment for chronic pain.[272]
- Respiratory depression, even at extremely high levels, does not occur in the context of appropriate clinical treatment.[273]
- There is no "ceiling dose" for opioids.[274]

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of Lynn R. Webster, MD, https://www.medscape.org/viewarticle/524538_2 (last visited Mar. 6, 2018).

[270] Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, Medscape, http://www.medscape.org/viewarticle/563417_6 (last visited Dec. 11, 2017).

[271] Brief of Amici the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain, 2005 WL 2405247, *8, *United States v. Hurowitz*, 459 F.3d 463 (4th Cir. 2006) (citing Portenoy et. al, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, PAIN, Vol. 25, 171-186, (1986)).

[272] *Id*. at *8, and sources cited in note 11.

[273] *Id*.

[274] *Id*.

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- Opioid analgesics are the most effective way to treat pain of moderate to severe intensity and often the only treatment that provides significant relief.[275]

- "Opioid rotations" (switching from one opioid to another) not only for cancer patients, but also for non-cancer patients, may need to occur four or five times over a person's "lifetime" to manage pain.[276]

- "Opioids represent a highly effective . . . class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief."[277]

> Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids—the gradual waning of relief at a given dose—and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.[3]

434. Members of the Opioid Marketing Enterprise created and championed the concept of "pseudoaddiction," advocating that signs of addiction were actually pseudoaddiction that required prescribing additional opioids:

- Patients might experience withdrawal symptoms associated with physical dependence as the decrease their dose, "[b]ut unlike actual addicts, such individuals, if they resume their opioid use, will only take enough medication to alleviate their pain."[278]

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[275] [275] Brief of Amici Russel K. Portenoy, *et al*., 2005 WL 2405249, *United States v. Hurwitz*, 459 F.3d 463.

[276] Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

[277] Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, 2007, https://www.painmedicinenews.com/download/BtoB_Opana_WM.pdf (last visited Mar. 8, 2018).

[278] Brief Amici Curiae of American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio Pain Initiative, in Support of Defendants/Appellants, *Howland v. Purdue Pharma, L.P., et al.*, Appeal No. CA 2002 09 0220 (Butler Co., Ohio 12th Court of Appeals,

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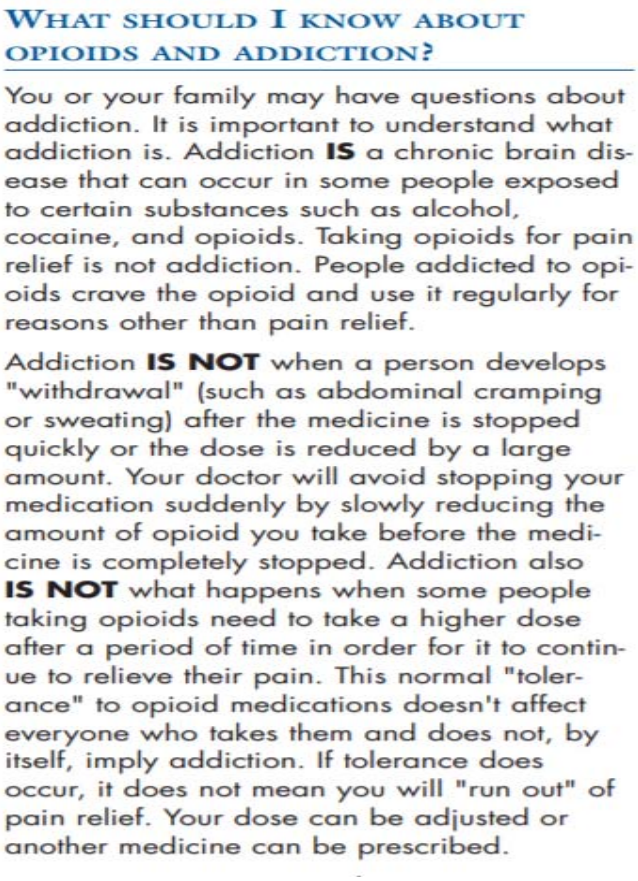
- "Addiction **IS NOT** when a person develops 'withdrawal' (such as abdominal cramping or sweating) after the medicine is stopped quickly or the dose is reduced by a large amount. . . . Addiction also **IS NOT** what happens when some people taking opioids need to take a higher dose after a period of time in order for it to continue to relieve their pain. This normal 'tolerance' to opioid medications doesn't affect everyone who takes them and does not, by itself, imply addiction."[279]



WHAT SHOULD I KNOW ABOUT OPIOIDS AND ADDICTION?

You or your family may have questions about addiction. It is important to understand what addiction is. Addiction **IS** a chronic brain disease that can occur in some people exposed to certain substances such as alcohol, cocaine, and opioids. Taking opioids for pain relief is not addiction. People addicted to opioids crave the opioid and use it regularly for reasons other than pain relief.

Addiction **IS NOT** when a person develops "withdrawal" (such as abdominal cramping or sweating) after the medicine is stopped quickly or the dose is reduced by a large amount. Your doctor will avoid stopping your medication suddenly by slowly reducing the amount of opioid you take before the medicine is completely stopped. Addiction also **IS NOT** what happens when some people taking opioids need to take a higher dose after a period of time in order for it to continue to relieve their pain. This normal "tolerance" to opioid medications doesn't affect everyone who takes them and does not, by itself, imply addiction. If tolerance does occur, it does not mean you will "run out" of pain relief. Your dose can be adjusted or another medicine can be prescribed.

Dec. 23, 2002), https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014-howland-apf-amicus.pdf.

[279] Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesic*s, Endo Pharmaceuticals (2004), http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf (emphasis in original) (last visited Mar. 9, 2018).

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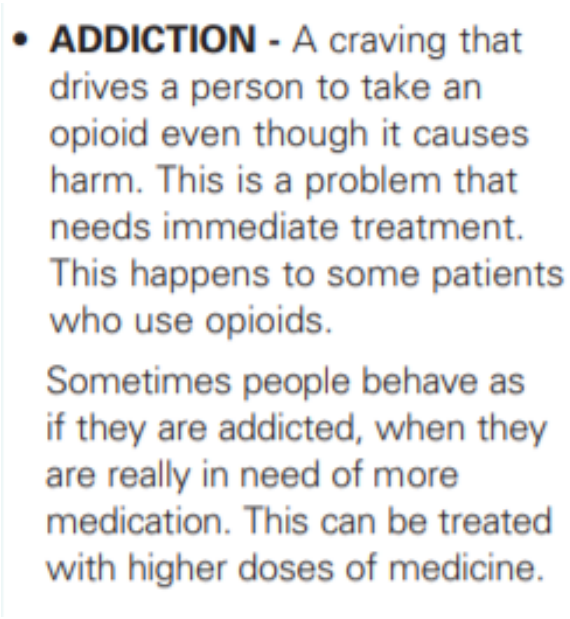
- Behaviors such as "[r]equesting [drugs] by name," "[d]emanding or manipulative behavior," "[o]btaining drugs from more than one physician," and "[h]oarding opioids," are all really signs of pseudoaddiction, rather than genuine addiction."[280]

- "Sometimes people behave as if they are addicted, when they are really in need of more medication."[281]



- For prescribers facing signs of aberrant behavior, increasing the does "in most cases . . . should be the clinician's first response."[282]

435. Members of the Opioid Marketing Enterprise advocated that long-term use of prescription opioids would improve function, including but not limited to, psychological health, and health-related quality of life:

- Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related

[280] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*, 8-9 (2007).

[281] *Pain: Opioid Facts*, http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patiented/pdf/Patient%20Education%20b380_b385%20%20pf%20opiod.pdf (last visited Mar. 6, 2018).

[282] Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain*, 59 (2007).

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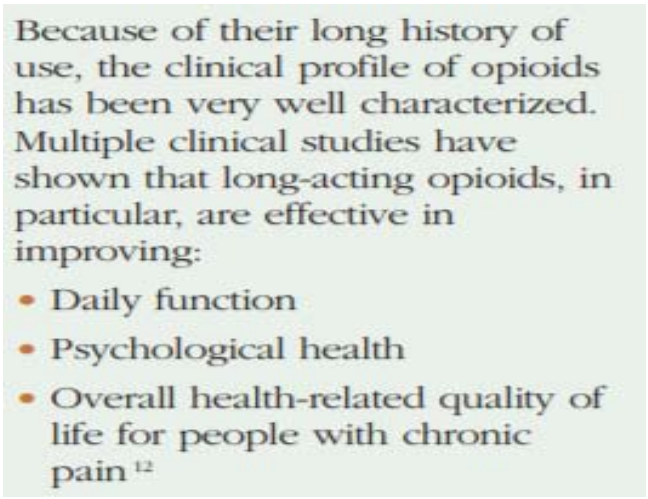
quality of life for chronic pain patients." The sole reference for the functional improvement claim noted the absence of long-term studies and actually stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids." The *Policymaker's Guide* is still available online.[283]


Because of their long history of use, the clinical profile of opioids has been very well characterized. Multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving:

- Daily function
- Psychological health
- Overall health-related quality of life for people with chronic pain [12]

- Opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins.[284]

- "[Y]our level of function should improve, you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse."[285]

- "The goal of opioid therapy is to . . . improve your function."[286]


The goal of opioid therapy is to control pain and improve your function.

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[283] *A Policymaker's Guide to Understanding Pain & Its Management*, American Pain Foundation (2011) at 5, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last visited Mar. 6, 2018).

[284] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*, 8-9 (2007); Scott M. Fishman, *Responsible Opioid Prescribing: A Clinician's Guide*, 10-11 (2d ed. 2012).

[285] Upon information and belief this misrepresentation was made on the website painknowledge.org.

[286] *Pain: Opioid Facts*, http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patiented/pdf/Patient%20Education%20b380_b385%20%20pf%20opiod.pdf (last visited Mar. 6, 2018).

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- The "goal" for chronic pain patients is to "improve effectiveness which is different from efficacy and safety."[287]

436. Members of the Opioid Marketing Enterprise represented that screening questions and professional guidelines would help curb addiction and potential abuse:

- Screening questions and professional guidelines will "easily and efficiently" allow physicians to manage risk and "minimize the potential for abuse."[288]

- Risk screening tools, urine testing, and patient agreements are a way to prevent "overuse of prescriptions" and "overdose deaths."[289]

[287] Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

[288] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*, 8-9 (2007).

[289] *See*, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, Emerging Solutions in Pain http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

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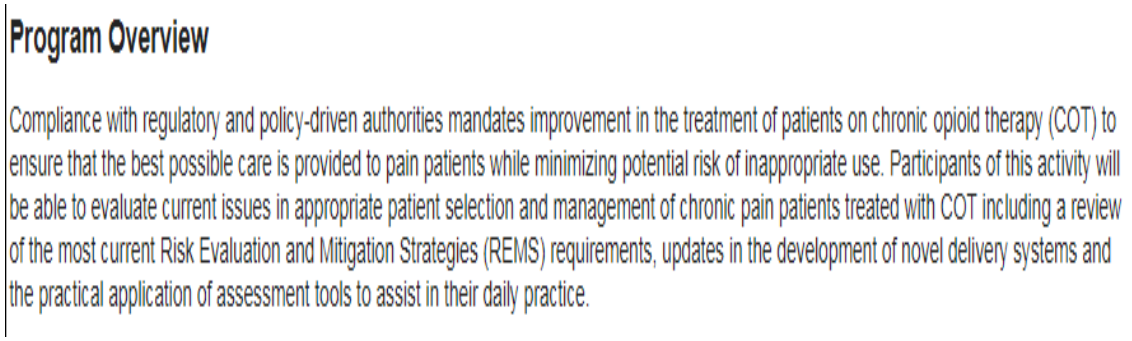

Program Overview

Compliance with regulatory and policy-driven authorities mandates improvement in the treatment of patients on chronic opioid therapy (COT) to ensure that the best possible care is provided to pain patients while minimizing potential risk of inappropriate use. Participants of this activity will be able to evaluate current issues in appropriate patient selection and management of chronic pain patients treated with COT including a review of the most current Risk Evaluation and Mitigation Strategies (REMS) requirements, updates in the development of novel delivery systems and the practical application of assessment tools to assist in their daily practice.

- The risks of addiction and abuse can be managed by doctors and evaluated with "tools."[290]

437. In addition to the unbranded marketing misrepresentations made by members of the Opioid Marketing Enterprise, the RICO Marketing Defendants made misrepresentations in their branded marketing activities. The RICO Marketing Defendants' branded marketing misrepresentations furthered the common purpose of the Opioid Marketing Enterprise because they advanced the common messages of the Opioid Marketing Enterprise.

438. The RICO Marketing Defendants misrepresented that opioids were non-addictive or posed less risk of addiction or abuse:

- **Purdue:**
    - "Fear of addiction is exaggerated."[291]

[290] Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

[291] Harriet Ryan, et al., "*You Want A Description of Hell?" OxyContin's 12-Hour Problem*, L.A. Times (May 5, 2016), http://documents.latimes.com/oxycontin-press-release-1996/ (hereinafter "Ryan, Description of Hell")

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The fear of addiction is exaggerated.

One cause of patient resistance to appropriate pain treatment -- the fear of addiction -- is largely unfounded. According to Dr. Max, "Experts agree that most pain caused by surgery or cancer can be relieved, primarily by carefully adjusting the dose of opioid (narcotic) pain reliever to each patient's need, and that there is very little risk of addiction from the proper uses of these drugs for pain relief."

Paul D. Goldenheim, M.D., Vice President of **Purdue Pharma** L.P. in Norwalk, Connecticut, agrees with this assessment. "Proper use of medication is an essential weapon in the battle against persistent pain. But too often fear, misinformation and poor communication stand in the way of their legitimate use."

- Long-acting, extended release formulations are safe and "less prone" to abuse by patients and addiction.[292]
- Consistently minimizing the risk of addiction in the use of opioids for the treatment of chronic non-cancer-related pain.[293]
- OxyContin is virtually non-addicting.[294]
- "Assur[ing] doctors – repeatedly and without evidence – that 'fewer than one per cent' of patients who took OxyContin became addicted."[295]

[292] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. Times (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html (hereinafter "Meier, Guilty Plea").

[293] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph*, Public Health Tragedy, 99(2) Am. J. Pub. Health 221-27 (Feb. 2009) (hereinafter, "Van Zee, Promotion and Marketing").

[294] Patrick Keefe, *The Family that Built an Empire of Pain*, New Yorker (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain

[295] *Id.*; *see also* "*I got my life back*," OxyContin Promotional Video, 1998, https://www.youtube.com/watch?v=Er78Dj5hyeI (last visited Mar. 8, 2018).

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- OxyContin was addiction resistant and had "abuse deterrent properties."[296]
- Misrepresented the risk of addiction using misleading and inaccurate promotions of OxyContin that were unsupported by science.[297]
- It was more difficult to extract the oxycodone from an OxyContin tablet for intravenous abuse.[298]
- OxyContin created fewer chances for addiction than immediate-release opioids.[299]
- OxyContin had fewer "peak and trough" effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids.[300]

[296] *Id.*

[297] Press Release, U.S. Attorney for the Western District of Virginia, Statement of United States Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executives for Illegally Misbranding OxyContin, at 5-6 (May 10, 2007), https://assets.documentcloud.org/documents/279028/purdue-guilty-plea.pdf.

[298] *Id.*

[299] *Id.*

[300] *Id.*

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- Patients could abruptly stop opioid therapy without experiencing withdrawal symptoms, and patients who took OxyContin would not develop tolerance.[301]

- OxyContin did not cause a "buzz," caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.[302]

- Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which under the heading, "Indications of Possible Drug Abuse," shows pictures of the stigmata of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa. In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through oral use. Thus, these misrepresentations wrongly reassured doctors that as long as they do not observe those signs, they need not worry that their patients are abusing or addicted to opioids.

- Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which asserted that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

- A Purdue-funded study with a Purdue co-author claimed that "evidence that the risk of psychological dependence or addiction is low in the absence of a history of substance abuse."[303] The study relied only on the 1980 Porter-Jick letter to the editor concerning a chart review of hospitalized patients, not patients taking Purdue's long-acting, take-home opioid. Although the term "low" is not defined, the overall presentation suggests the risk is so low as not to be a worry.

- Purdue sales representatives told prescribers that its drugs were "steady state," the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.

- Purdue sales representatives told prescribers that Butrans has a lower abuse potential than other drugs because it was essentially tamperproof and, after a certain point, patients no longer experience a "buzz" from increased dosage.

- Advertisements that Purdue sent to prescribers stated that OxyContin ER was less likely to be favored by addicts, and, therefore, less likely to be abused or diverted, or result in addiction.

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[301] *Id*.

[302] *Id*.

[303] C. Peter N. Watson et al., *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial I painful diabetic neuropathy*, 105 Pain 71 (2003).

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- In discussions with prescribers, Purdue sales representatives omitted discussion of addiction risks related to Purdue's drugs.

- **Janssen:**

  - **Myth**: Opioid medications are always addictive.
    Fact: Many studies show that opioids are rarely addictive when used properly for the management of chronic pain.[304]

  - **Myth**: Opioid doses have to get bigger over time because the body gets used to them.
    Fact: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.[305]

  - "[Q]uestions of addiction," "are often overestimated" because, "[a]ccording to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesics."[306]

Other Opioid Analgesic Concerns
Aside from medical issues related to opioid analgesics, there are nonmedical issues that may have an impact on prescribing patterns and patient use of these drugs. Practitioners are often concerned about prescribing opioid analgesics due to potential legal issues and questions of addiction.[15,16] By the same token, patients report similar concerns about developing an addiction to opioid analgesics.[17] While these concerns are not without some merit, it would appear that they are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesics analgesic therapy.[18]

  - Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and which its sales force distributed. This guide described a "myth" that opioids are addictive, and asserts as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." Although the term "rarely" is not defined, the overall presentation suggests the risk is so low as

[304] *Finding Relief, Pain Management for Older Adults*, (2009) (emphasis in original).

[305] *Finding Relief, Pain Management for Older Adults*, (2009).

[306] *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/opioid-pain-management (last visited Dec. 11, 2017).

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not to be a worry. The language also implies that as long as a prescription is given, opioid use is not a problem.

- Janssen contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." The study supporting this assertion does not analyze addiction rates by age and, as already noted, addiction remains a significant risk for elderly patients. Janssen was aware of the AGS guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion.

- Janssen provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught that [l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests the risk is so low as not to be a worry.

- Janssen currently runs a website, Prescriberesponsibly.com (last modified July 2, 2015), which claims that concerns about opioid addiction are "overstated."

- A June 2009 Nucynta Training module warns Janssen's sales force that physicians are reluctant to prescribe controlled substances like Nucynta, but this reluctance is unfounded because "the risks . . . are much smaller than commonly believed."

- Janssen sales representatives told prescribers that its drugs were "steady state," the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.

- Janssen sales representatives told prescribers that Nucynta and Nucynta ER were "not opioids," implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to Janssen's drugs. In truth, however, as set out in Nucynta's FDA-mandated label, Nucynta "contains tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit."

- Janssen's sales representatives told prescribers that Nucynta's unique properties eliminated the risk of addiction associated with the drug.

- In discussions with prescribers, Janssen sales representatives omitted discussion of addiction risks related to Janssen's drugs.

- **Cephalon:**

  - Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which claims, among other things, that

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"patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids."

- Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

- In discussions with prescribers, Cephalon sales representatives omitted any discussion of addiction risks related to Cephalon's drugs.

- **Endo:**

  - "[P]atients treated with prolonged opioid medicines usually do not become addicted."[307]

  - Endo trained its sales force in 2012 that use of long-acting opioids resulted in increased patient compliance, without any supporting evidence.

  - Endo's advertisements for the 2012 reformulation of Opana ER claimed it was designed to be crush resistant,[308] in a way that conveyed that it was less likely to be abused. This claim was false; the FDA warned in a May 10, 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse" and Endo's "post-marketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse." Further, Endo instructed its sales representatives to repeat this claim about "design," with the intention of conveying Opana ER was less subject to abuse.

  - Endo sponsored a website, painknowledge.com, through APF and NIPC, which claimed in 2009 that: "[p]eople who take opioids as prescribed usually do not become addicted." Although the term "usually" is not defined, the overall presentation suggests the risk is so low as not to be a worry. The language also implies that as long as a prescription is given, opioid use will not become problematic. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it.

  - Endo sponsored a website, PainAction.com, which stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

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[307] *Id.*

[308] *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No. 15-228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15, at 5 (Mar. 1, 2016), https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

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- Endo sponsored CMEs published by APF's NIPC, of which Endo was the sole funder, titled *Persistent Pain in the Older Adult and Persistent Pain in the Older Patient*. These CMEs claimed that opioids used by elderly patients present "possibly less potential for abuse than in younger patients[,]"[309] which lacks evidentiary support and deceptively minimizes the risk of addiction for elderly patients.

- Endo distributed an education pamphlet with the Endo logo titled *Living with Someone with Chronic Pain*, which inaccurately minimized the risk of addiction: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."

- Endo distributed a patient education pamphlet edited by key opinion leader Dr. Russell Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics*. It claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems."[310] This implies that pain patients prescribed opioids will not become addicted, which is unsupported and untrue.

- Endo contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids, and there is no such evidence. Endo was aware of the AGS guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion.

- Endo sales representatives told prescribers that its drugs were "steady state," the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.

- Endo provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests that the risk is so low as not to be a worry.

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[309] NIPC, *Persistent Pain and the Older Patient* (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20Invite.pdf.

[310] Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesic*s, Endo Pharmaceuticals (2004), https://www.yumpu.com/en/document/view/35479278/understanding-your-pain-taking-oral-opioid-analgesics (last visited Mar. 8, 2018).

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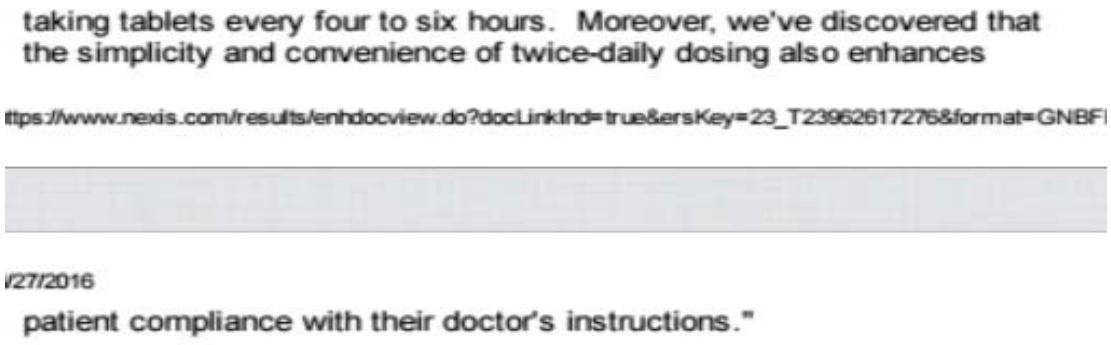
- In discussions with prescribers, Endo sales representatives omitted discussion of addiction risks related to Endo's drugs.

439. The RICO Marketing Defendants misrepresented that opioids improved function and quality of life:

- **Purdue:**
  - "[W]e've discovered that the simplicity and convenience of twice-daily dosing also enhances patient compliance with their doctor's instructions."[311]


taking tablets every four to six hours. Moreover, we've discovered that the simplicity and convenience of twice-daily dosing also enhances

ttps://www.nexis.com/results/enhdocview.do?docLinkInd=true&ersKey=23_T23962617276&format=GNBFI

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patient compliance with their doctor's instructions."

  - Purdue ran a series of advertisements for OxyContin in 2012 in medical journals titled "Pain vignettes," which were case studies featuring patients, each with pain conditions persisting over several months, recommending OxyContin for each. One such patient, "Paul," is described to be a "54-year-old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work more effectively.
  - Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The sole reference for the functional improvement claim noted the absence of long-term studies and actually stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids." *The Policymaker's Guide* is still available online.
  - Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids, when used properly, "give [pain patients] a quality of life we deserve." APF distributed 17,200 copies in one year

[311] *Ryan, Description of Hell*, http://documents.latimes.com/oxycontin-press-release-1996/

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alone, according to its 2007 annual report, and the guide currently is available online.

- Purdue sponsored APF's *Exit Wounds* (2009), which taught veterans that opioid medications "increase your level of functioning." Exit Wounds also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.

- Purdue sponsored the FSMB's Responsible Opioid Prescribing (2007), which taught that relief of pain itself improved patients' function. Responsible Opioid Prescribing explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Purdue also spent over $100,000 to support distribution of the book.

- **Janssen:**

  - Misrepresented that patients experienced "[s]ignificantly reduced nighttime awakenings."[312]

  - Misrepresented "[s]ignificant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index."[313]

  - Misrepresented "[s]ignificant improvement in social functioning."

  - Misrepresented outcome claims that were misleading because they lacked substantial support, evidence or clinical experience and "impl[ied] that patients will experience improved social or physical functioning or improved work productivity when using Duragesic," including: "1,360 loaves . . . and counting, [w]ork, uninterrupted, [l]ife, uninterrupted, [g]ame, uninterrupted, [c]hronic pain relief that supports functionality, [h]elps patients think less about their pain, and [i]mprove[s] . . . physical and social functioning."[314]

  - Misrepresented that "[o]pioid analgesics, for example, have no true 'ceiling dose' for analgesia and do not cause direct organ damage."[315]

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[312] NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutica (Mar. 30, 2000) at 2.

[313] *Id*.

[314] *Id*. at 3 (internal quotations omitted).

[315] *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/opioid-pain-management (last visited Dec. 11, 2017).

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> *Use of Opioid Analgesics in Pain Management*
> Opioid analgesics are often the first line of treatment for many painful conditions and may offer advantages over nonsteroidal anti-inflammatory drugs (NSAIDs). Opioid analgesics, for example, have no true "ceiling dose" for analgesia and do not cause direct organ damage; however, they do have several possible side effects, including constipation, nausea, vomiting, a decrease in sexual interest, drowsiness, and respiratory depression. With the exception of constipation, many patients often develop tolerance to most of the opioid analgesic-related side effects.[8]

- **Myth**: Opioids make it harder to function normally.
  Fact: When used correctly for appropriate conditions, opioids may make it *easier* for people to live normally.[316]

- Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it easier for people to live normally." The myth/fact structure implies authoritative backing for the claim that does not exist. The targeting of older adults also ignored heightened opioid risks in this population.

- Janssen sponsored, developed, and approved content of a website, *Let's Talk Pain* in 2009, acting in conjunction with the APF and AAPM whose participation in Let's Talk Pain Janssen financed and orchestrated. This website featured an interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," inaccurately implying her experience would be representative. This video is still available today on youtube.com.

- Janssen provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications "increase your level of functioning" (emphasis in the original). Exit Wounds also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.

- **Cephalon:**

  - Cephalon sponsored the FSMB's Responsible Opioid Prescribing (2007), which taught that relief of pain itself improved patients' function.

[316] *Finding Relief, Pain Management for Older Adults*, (2009) (emphasis in original).

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Responsible Opioid Prescribing explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed the book through its pain sales force to 10,000 prescribers and 5,000 pharmacists.

- Cephalon sponsored the American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids when used properly "give [pain patients] a quality of life we deserve." The *Treatment Options* guide notes that non-steroidal anti-inflammatory drugs have greater risks with prolonged duration of use, but there was no similar warning for opioids. APF distributed 17,200 copies in one year alone, according to its 2007 annual report, and the publication is currently available online.

- Cephalon sponsored a CME written by Dr. Webster, titled Optimizing Opioid Treatment for Breakthrough Pain, which was offered online by Medscape, LLC from September 28, 2007, through December 15, 2008. The CME taught that Cephalon's Actiq and Fentora improve patients' quality of life and allow for more activities when taken in conjunction with long-acting opioids.

- **Endo:**

  - Opana ER "will benefit patients, physicians and payers."[317]

"Patient safety is our top concern and addressing appropriate use of opioids is a responsibility that we take very seriously. We firmly believe this new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."

  - "Endo distributed a pamphlet in New York and posted on its public website, www.opana.com, photographs of purported Opana ER patients that implied that patients can achieve higher function with Opana ER."[318]

  - Endo sponsored a website, painknowledge.com, through APF and NIPC, which claimed in 2009 that with opioids, "your level of function should improve; you may

[317] *FDA Approves Endo Pharmaceuticals' Crush-Resistant Opana ER*, December 12, 2011, https://www.biospace.com/article/releases/fda-approves-endo-pharmaceuticals-crush-resistant-opana-er-/.

[318] *Id*. at 8.

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find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse."

- A CME sponsored by Endo, titled *Persistent Pain in the Older Patient*, taught that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

- Endo distributed handouts to prescribers that claimed that use of Opana ER to treat chronic pain would allow patients to perform work as a chef. This flyer also emphasized Opana ER's indication without including equally prominent disclosure of the "moderate to severe pain" qualification.

- Endo's sales force distributed FSMB's *Responsible Opioid Prescribing* (2007). This book taught that relief of pain itself improved patients' function. Responsible Opioid Prescribing explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course."

- Endo provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications "increase your level of functioning" (emphasis in the original). Exit Wounds also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.

440. The RICO Marketing Defendants misrepresented that addiction risks can be avoided or managed through screening tools and prescription guidelines:

- **Purdue:**

  - Purdue's unbranded website, "In the Face of Pain" (inthefaceofpain.com), states that policies that "restrict[] access to patients with pain who also have a history of substance abuse" and "requiring special government-issued prescription forms for the only medications that are capable of relieving pain that is severe" are "at odds with" best medical practices.[319]

  - Purdue sponsored a 2012 CME program taught by a KOL titled *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. This presentation recommended that use of screening tools, more frequent refills, and switching opioids could treat a high-risk patient showing signs of potentially addictive behavior.

[319] *See* In the Face of Pain Fact Sheet: Protecting Access to Pain Treatment, Purdue Pharma L.P. (Resources verified Mar. 2012), www.inthefaceofpain.com/content/uploads/2011/12/factsheet_ProtectingAccess.pdf.

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- Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This publication taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

- Purdue sales representatives told prescribers that screening tools can be used to select patients appropriate for opioid therapy and to manage the risks of addiction.

- **Cephalon:**

  - Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."

- **Endo:**

  - Endo paid for a 2007 supplement[320] available for continuing education credit in the Journal of Family Practice and written by a doctor who later became a member of Endo's speakers' bureau. This publication, titled *Pain Management Dilemmas in Primary Care*, recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain, and advised that patients at high risk of addiction could receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

441. The RICO Marketing Defendants misrepresented that signs of opioid addiction were not addiction, withdrawal could be simply managed, and promoted the concept of pseudoaddiction:

- **Purdue:**

  - Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

  - Purdue distributed to physicians, at least as of November 2006 and posted on its unbranded website, Partners Against Pain, a pamphlet copyrighted 2005 and titled *Clinical Issues in Opioid Prescribing*. This pamphlet included a list of conduct including "illicit drug use and deception" it defined as indicative of

[320] The Medical Journal, The Lancet found that all of the supplement papers it received failed peer-review. Editorial, "*The Perils of Journal and Supplement Publishing*," 375 The Lancet 9712 (347) 2010.

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pseudoaddiction or untreated pain. It also states: "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated. . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."

- Purdue sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name, "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction. Purdue also spent over $100,000 to support distribution of the book.

- Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which states: "Pseudo-addiction describes patient behaviors that may occur when pain is undertreated. . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated."

- *A Policymaker's Guide to Understanding Pain & Its Management* also taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the significant hardships that often accompany cessation of use.

- Purdue sales representatives told prescribers that the effects of withdrawal from opioid use can be successfully managed.

- Purdue sales representatives told prescribers that the potential for withdrawal on Butrans was low due to Butrans' low potency and its extended release mechanism.

- **Janssen:**

  - Janssen's website, Let's Talk Pain, stated from 2009 through 2011 that "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated" and "[p]seudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

  - A Janssen PowerPoint presentation used for training its sales representatives titled "*Selling Nucynta ER*" indicates that the "low incidence of withdrawal symptoms" is a "core message" for its sales force. This message is repeated in numerous Janssen training materials between 2009 and 2011. The studies supporting this claim did not describe withdrawal symptoms in patients taking Nucynta ER beyond 90 days or at high doses and would therefore not be representative of withdrawal symptoms in the chronic pain population. Patients on opioid therapy long-term and at high doses will have a harder time discontinuing the drugs and are more likely to experience withdrawal symptoms. In addition, in claiming a low rate of withdrawal symptoms, Janssen relied upon a study that only began tracking withdrawal symptoms in patients two to four days after discontinuing opioid use, when Janssen

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knew or should have known that these symptoms peak earlier than that for most patients. Relying on data after that initial window painted a misleading picture of the likelihood and severity of withdrawal associated with chronic opioid therapy. Janssen also knew or should have known that the patients involved in the study were not on the drug long enough to develop rates of withdrawal symptoms comparable to rates of withdrawal suffered by patients who use opioids for chronic pain—the use for which Janssen promoted Nucynta ER.

- Janssen sales representatives told prescribers that patients on Janssen's drugs were less susceptible to withdrawal than those on other opioids.

- **Cephalon:**

  - Cephalon sponsored FSMB's Responsible Opioid Prescribing (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of pseudoaddiction. Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed it through its pain sales force to 10,000 prescribers and 5,000 pharmacists.

- **Endo:**

  - Endo distributed copies of a book by KOL Dr. Lynn Webster entitled *Avoiding Opioid Abuse While Managing Pain* (2007). Endo's internal planning documents describe the purpose of distributing this book as to "[i]ncrease the breadth and depth of the Opana ER prescriber base." The book claims that when faced with signs of aberrant behavior, the doctor should regard it as pseudoaddiction and thus, increasing the dose in most cases . . . should be the clinician's first response."

  - Endo spent $246,620 to buy copies of FSMB's *Responsible Opioid Prescribing* (2007), which was distributed by Endo's sales force. This book asserted that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction."

  - A CME sponsored by Endo, titled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering the dose by 10-20% per day for ten days.

  - Endo misrepresented that "symptoms of withdrawal do not indicate addiction."[321]

[321] *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No. 15-228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15, at 7 (Mar. 1, 2016), https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

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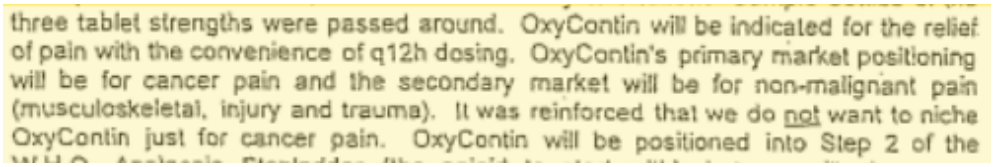
- "Endo also trained its sales representatives to distinguish addiction from 'pseudoaddiction.'"[322]

442. The RICO Marketing Defendants misrepresented that opioids were safe for the long-term treatment of chronic, non-acute, and non-cancer pain:

- **Purdue:**
  - "[W]e do not want to niche OxyContin just for cancer pain."[323]


three tablet strengths were passed around. OxyContin will be indicated for the relief of pain with the convenience of q12h dosing. OxyContin's primary market positioning will be for cancer pain and the secondary market will be for non-malignant pain (musculoskeletal, injury and trauma). It was reinforced that we do not want to niche OxyContin just for cancer pain. OxyContin will be positioned into Step 2 of the

  - OxyContin should be prescribed not merely for severe short-term pain associated with surgery or cancer, but also for less acute, longer-lasting pain like arthritis, back pain, sports injuries, fibromyalgia with almost limitless treatment potential.[324]

- **Janssen:**
  - Duragesic was "more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence."[325]
  - Duragesic was "not just for end stage cancer anymore" when the FDA only approved Duragesic for "the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by lesser means."[326]
  - Misrepresented that "Duragesic can be used for any type of pain management" despite the fact that the FDA approved warning stated that "BECAUSE SERIOUS OR LIFE-THREATENING HYPOVENTILATION COULD OCCUR, DURAGESIC® (FENTANYL TRANSDERMAL SYSTEM) IS

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[322] *Id.*

[323] Ryan, *Description of Hell*, http://documents.latimes.com/oxycontin-launch-1995/ (emphasis in the L.A. Times document).

[324] Patrick Keefe, *The Family that Built an Empire of Pain*, New Yorker (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain

[325] NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutica (Mar. 30, 2000) at 2.

[326] *Id.*

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CONTRAINDICATED: In the management of acute or post-operative pain, including use in outpatient surgeries . . . ."[327]

- Misrepresented "numerous claims for the efficacy and safety of Duragesic," but failed to "present[] any risk information concerning the boxed warnings, contraindications, warnings, or side effects associated with Duragesic's use . . . [and] . . . fail[ed] to address important risks and restrictions associated with Duragesic therapy."[328]

- Misrepresented "[d]emonstrated effectiveness in chronic back pain with additional patient benefits, . . . 86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep."[329]

- **Cephalon:**

  - "[P]romoting [Actiq] for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy."[330]

  - "[P]romot[ing] Actiq for use in patients who were not yet opioid-tolerant, and for whom it could have life-threatening results."[331]

  - In 2011, Cephalon wrote an article titled "*2011 Special Report: An Integrated Risk Evaluation and Risk Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA®) AND Oral Transmucosal Fentanyl Citrate (Actiq®)*, published in *Pain Medicine News*. Upon information and belief, Cephalon misrepresented that its drugs were "shown to be effective in treatment of [break through pain] associated with multiple causes of pain," not just cancer.

443. The RICO Marketing Defendants also misrepresented that opioids were safer that non-opioid analgesics because there is no ceiling dose for opioid treatment.

- **Purdue:**

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[327] *Id*.

[328] *Id*.

[329] *Id*. at 2-3.

[330] Press Release, U.S. Department of Justice, Pharmaceutical Company Cephalon To Pay $425 Million For Off-Label Drug Marketing (Sept. 29, 2008), https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonrelease.pdf.

[331] *Id*.

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- Purdue's "In the Face of Pain" website, along with initiatives of APF, promoted the notion that if a patient's doctor does not prescribe them what—in their view—is a sufficient dose of opioids, they should find another doctor who will. In so doing, Purdue exerted undue, unfair, and improper influence over prescribers who face pressure to accede to the resulting demands.

- Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are "sometimes necessary," even indefinitely high ones, which suggested that high dose opioids are safe and appropriate and did not disclose the risks from high dose opioids. This publication is still available online.

- Purdue sponsored APF's T*reatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The guide also claimed that some patients "need" a larger dose of the drug, regardless of the dose currently prescribed. This language fails to disclose heightened risks at elevated doses.

- *Treatment Options*, also taught that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. *Treatment Options* continued, warning that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose.

- Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013. The CME, *Overview of Management Options*, was edited by KOL Dr. Russell Portenoy, among others, and taught that other drugs, but not opioids, are unsafe at high doses. The 2013 version is still available for CME credit.

- *Overview of Management Options* also taught NSAIDs and other drugs, but not opioids, are unsafe at high doses.

- Purdue sponsored APF's *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Exit Wounds also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.

- Purdue sales representatives told prescribers that opioids were just as effective for treating patients long-term and omitted any discussion that increased tolerance would require increasing, and increasingly dangerous, doses.

- Purdue sales representatives told prescribers that NSAIDs were more toxic than opioids.

- **Janssen:**

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- Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This guide listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased doses from opioids. The publication also falsely claimed that it is a "myth" that "opioid doses have to be bigger over time."

- *Finding Relief: Pain Management for Older Adults* also described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "can increase the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness," which the brochure claims will go away, and constipation.

- Janssen sponsored APF's *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines. Janssen's label for Duragesic, however, states that use with benzodiazepines "may cause respiratory depression, [low blood pressure], and profound sedation or potentially result in coma. Exit Wounds also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.

- Janssen sales representatives told prescribers that Nucynta was not an opioid, making it a good choice for chronic pain patients who previously were unable to continue opioid therapy due to excessive side effects. This statement was misleading because Nucynta is an opioid and has the same effects as other opioids.

- **Cephalon:**

  - Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of their opioid, regardless of the dose currently prescribed.

  - *Treatment Options*, also taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. *Treatment Options* continued, warning that risks of NSAIDs increase if "taken more than a period of months." With no corresponding warning about opioids. The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose.

  - Cephalon sponsored a CME written by KOL Dr. Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids that include aspirin and acetaminophen are less effective to treat breakthrough pain because of dose limitations.

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- Cephalon sales representatives assured prescribers that opioids were safe, even at high doses.

- Cephalon sales representatives told prescribers that NSAIDs were more toxic than opioids.

- "[P]romot[ing] Actiq for use in patients who were not yet opioid tolerant, and for whom it could have life-threatening results."[332]

- **Endo:**

  - Endo sponsored a website, painknowledge.com, through APF and NIPC, which claimed in 2009 that opioids may be increased until "you are on the right dose of medication for your pain," and once that occurs, further dose increases would not occur.

  - Through painknowledge.com Endo distributed a flyer called "Pain: Opioid Therapy." This publication included a list of adverse effects from opioids that omitted significant adverse effects like hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

  - Endo provided grants to APF to distribute Exit Wounds (2009), which omitted warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Exit Wounds also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.

  - Endo sales representatives told prescribers that NSAIDs were more toxic than opioids.

  - Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked: "If I take the opioid now, will it work later when I really need it?" The response was: "The dose can be increased . . . . You won't 'run out' of pain relief."

  - Endo distributed a "case study" to prescribers titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. The study cites an example, meant to be representative, of a patient "with a massive upper gastrointestinal bleed believed to be related to his protracted use of NSAIDs" (over eight years), and recommends treating with opioids instead.

[332] *Id.*

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444. These misrepresentations, and the legion of other representations made by the RICO Marketing Defendants and members of Opioid Marketing Enterprise, all furthered the common purpose and fraudulent scheme of the Opioid Marketing Enterprise. But they were demonstrably false, as confirmed by investigations and enforcement actions against the RICO Marketing Defendants.

445. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay $600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. The Order adopting the guilty pleas provide:

> effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;
>
> d. Told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and
>
> e. Told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.
>
> (Information ¶ 19.) Purdue has agreed that these facts are true, and the individual defendants, while they do not agree that they had knowledge of these things, have agreed that the court may accept these facts in support of their guilty pleas. (Agreed Statement of Facts ¶ 46.)

446. Additionally, Michael Friedman ("Friedman"), the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R. Udell ("Udell"), Purdue's top lawyer, also pled guilty and agreed to pay $8 million in fines; and Paul D.

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Goldenheim ("Goldenheim"), its former medical director, pled guilty as well and agreed to pay $7.5 million in fines.[333]

447. In a statement announcing the guilty plea, John Brownlee ("Brownlee"), the U.S. Attorney for the Western District of Virginia, stated:

> Purdue claimed it had created the miracle drug – a low risk drug that could provide long acting pain relief but was less addictive and less subject to abuse. Purdue's marketing campaign worked, and sales for OxyContin skyrocketed – making billions for Purdue and millions for its top executives.
>
> But OxyContin offered no miracles to those suffering in pain. Purdue's claims that OxyContin was less addictive and less subject to abuse and diversion were false – and Purdue knew its claims were false. The result of their misrepresentations and crimes sparked one of our nation's greatest prescription drug failures. . . . OxyContin was the child of marketers and bottom line financial decision making.[334]

448. Brownlee characterized Purdue's criminal activity as follows:

> First, Purdue trained its sales representatives to falsely inform health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse. Purdue ordered this training even though its own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet by simply crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.
>
> Second, Purdue falsely instructed its sales representatives to inform health care providers that OxyContin could create fewer chances for addiction than immediate-release opioids.
>
> Third, Purdue sponsored training that falsely taught Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids.

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[333] Press Release, U.S. Attorney for the Western District of Virginia, Statement of United States Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executives for Illegally Misbranding OxyContin (May 10, 2007), https://assets.documentcloud.org/documents/279028/purdue-guilty-plea.pdf.

[334] *Id.*

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> Fourth, Purdue falsely told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug.
>
> And fifth, Purdue falsely told health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.[335]

449. Similarly, Endo's marketing of Purdue was criticized and punished by the FDA and New York Attorney General.

450. On February 18, 2017, the State of New York announced a settlement with Endo requiring it "to cease all misrepresentations regarding the properties of Opana ER [and] to describe accurately the risk of addiction to Opana ER."[336] In the Assurance of Discontinuance that effectuated the settlement, the State of New York stated that Endo knew about the risks arising from the reformulated Opana ER even before it received FDA approval. Among other things, the investigation concluded that:

- Endo improperly marketed Opana ER as designed to be crush resistant, when Endo's own studies dating from 2009 and 2010 showed that the pill could be crushed and ground;
- Endo improperly instructed its sales representatives to diminish and distort the risks associated with Opana ER, including the serious danger of addiction; and
- Endo made unsupported claims comparing Opana ER to other opioids and failed to disclose accurate information regarding studies addressing the negative effects of Opana ER.[337]

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[335] *Id.*

[336] Press Release, Attorney General Eric T. Schneiderman, A.G. Schneiderman Announces Settlement With Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing Of Prescription Opioid Drugs (Mar. 3, 2016), https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals (last visited Mar. 9, 2018).

[337] *Id.*

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451. The 2017 settlement also identified and discussed a February 2013 communication from a consultant hired by Endo to the company, in which the consultant concluded that "'[t]he initial data presented do not necessarily establish that the reformulated Opana ER is tamper resistant.'" The same consultant also reported that the distribution of the reformulated Opana ER had already led to higher levels of abuse of the drug via injection.[338]

452. The Office of the Attorney General of New York also revealed that the "managed care dossier" Endo provided to formulary committees of healthcare plans and pharmacy benefit managers misrepresented the studies that had been conducted on Opana ER. According to Endo's vice president for pharmacovigilance and risk management, the dossier was presented as a complete compendium of all research on the drug. However, it omitted certain studies: Study 108 (completed in 2009) and Study 109 (completed in 2010), which showed that reformulated Opana ER could be ground and chewed.

453. The settlement also detailed Endo's false and misleading representations about the non-addictiveness of opioids and Opana. For example, until April 2012, Endo's website for the drug, www.opana.com, contained the following representation: "'Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.'"[339] However, Endo neither conducted nor possessed a survey demonstrating that most healthcare providers who treat patients with pain agree with that representation.

454. The Office of the Attorney General of New York also disclosed the following facts that it determined violated Opana's obligations to truthfully market its products:

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[338] *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance of Discontinuance No. 15-228, at 6 (New York, Mar. 1, 2016).

[339] *Id.* at 8.

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a. Training materials provided by Endo to sales representatives stated: "'Symptoms of withdrawal do not indicate addiction.'"[340] This representation is inconsistent with the diagnosis of opioid-use disorder as provided in the Diagnostic and Statistical Manual of Mental Disorders by the American Psychiatric Association (Fifth Edition).

b. Endo trained its sales representatives to falsely distinguish addiction from "pseudoaddiction," which it defined as a condition in which patients exhibit drug-seeking behavior that resembles but is not the same as addiction. Endo's vice president for pharmacovigilance and risk management testified that he was not aware of any research validating the concept of pseudoaddiction.

455. On June 9, 2017, the FDA asked Endo to voluntarily cease sales of Opana ER after determining that the risks associated with its abuse outweighed the benefits. According to Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, the risk associated with use of the product included "Injunction abuse . . . associated with a serious outbreak of HIV and hepatitis C, as well as cases of a serious blood disorder (thrombotic microangiopathy)." She noted that abuse of the reformulated Opana ER had resulted in "a serious disease outbreak."[341] If Endo did not comply, the FDA stated that it "intends to take steps to formally require its removal by withdrawing approval."[342]

456. Like Purdue and Endo, Janssen was the subject of an FDA enforcement action that identified its marketing statements as misrepresentations. For example:

457. On February 15, 2000, the FDA sent Janssen a letter concerning the alleged dissemination of "homemade" promotional pieces that promoted Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA

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[340] *Id*. at 7.

[341] *FDA requests removal of Opana ER for risks related to abuse*, June 8, 2017, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.

[342] *Id*.

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explained that the "homemade" promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance."[343]

458. The March 30, 2000 letter identified specific violations, including misrepresentations that Duragesic had a low potential for abuse:

> You present the claim, "Low abuse potential!" This claim suggests that Duragesic has less potential for abuse than other currently available opioids. However, this claim has not been demonstrated by substantial evidence. Furthermore, this claim is contradictory to information in the approved product labeling (PI) that states, "Fentanyl is a Schedule II controlled substance and can produce drug dependence similar to that produced by morphine." Therefore, this claim is false or misleading.[344]

459. The March 30, 2000 letter also stated that the promotional materials represented that Duragesic was "more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence."[345] Specifically, the FDA stated that Janssen was marketing Duragesic for indications other than the treatment of chronic pain that cannot otherwise be managed, for which it was approved:

> You present the claim, "It's not just for end stage cancer anymore!" This claim suggests that Duragesic can be used for any type of pain management. However, the PI for Duragesic states, "Duragesic (fentanyl transdermal system) is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by lesser means . . . ." Therefore, the suggestion that Duragesic can be used for any type of pain management promotes Duragesic[] for a much broader use than is recommended in the PI, and thus, is misleading. In addition, the suggestion that Duragesic can be used to treat any kind of pain is contradictory to the boxed warning in the PI. Specifically, the PI states,

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[343] NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutica (Mar. 30, 2000) at 2.

[344] *Id.*

[345] *Id.*

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> BECAUSE SERIOUS OR LIFE-THREATENING HYPOVENTILATION COULD OCCUR, DURAGESIC® (FENTANYL TRANSDERMAL SYSTEM) IS CONTRAINDICATED: In the management of acute or post-operative pain, including use in outpatient surgeries . . . .[346]

460. The March 30, 2000 letter also stated Janssen failed to adequately present "contraindications, warnings, precautions, and side effects with a prominence and readability reasonably comparable to the presentation of information relating to the effectiveness of the product."[347]

> Although this piece contains numerous claims for the efficacy and safety of Duragesic, you have not presented any risk information concerning the boxed warnings, contraindications, warnings, precautions, or side effects associated with Duragesic's use . . . . Therefore, this promotional piece is lacking in fair balance, or otherwise misleading, because it fails to address important risks and restrictions associated with Duragesic therapy.[348]

461. On September 2, 2004, the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic," including, specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products."

462. The September 2, 2004 letter warned Janssen regarding its claims that Duragesic had a low reported rate of mentions in the Drug Abuse Warning Network ("DAWN") as compared to other opioids. The letter stated that the claim was false or misleading because the claim was not based on substantial data and because the lower rate of mentions was likely attributable to Duragesic's lower frequency of use compared to other opioids listed in DAWN:

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[346] *Id*. at 2-3.

[347] *Id*. at 3 (emphasis in original).

[348] *Id*. at 3 (emphasis in original).

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> The file card presents the prominent claim, "Low reported rate of mentions in DAWN data," along with Drug Abuse Warning Network (DAWN) data comparing the number of mentions for Fentanyl/combinations (710 mentions) to other listed opioid products, including Hydrocodone/combinations (21,567 mentions), Oxycodone/combinations (18,409 mentions), and Methadone (10,725 mentions). The file card thus suggests that Duragesic is less abused than other opioid drugs.
>
> This is false or misleading for two reasons. First, we are not aware of substantial evidence or substantial clinical experience to support this comparative claim. The DAWN data cannot provide the basis for a valid comparison among these products. As you know, DAWN is not a clinical trial database. Instead, it is a national public health surveillance system that monitors drug-related emergency department visits and deaths. If you have other data demonstrating that Duragesic is less abused, please submit them.
>
> Second, Duragesic is not as widely prescribed as other opioid products. As a result, the relatively lower number of mentions could be attributed to the lower frequency of use, and not to a lower incidence of abuse. The file card fails to disclose this information.[349]

463. The September 2, 2004 letter also detailed a series of unsubstantiated false or misleading claims regarding Duragesic's effectiveness. The letter concluded that various claims made by Janssen were insufficiently supported, including:

- "'Demonstrated effectiveness in chronic back pain with additional patient benefits, . . . 86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep.'"
- "'All patients who experienced overall benefit from DURAGESIC would recommend it to others with chronic low back pain.'"
- "'Significantly reduced nighttime awakenings.'"
- "'Significant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index.'"
- "'Significant improvement in physical functioning summary score.'"

[349] Warning Letter from Thomas W. Abrams, U.S. Department of Health and Human Services, to Ajit Shetty, Janssen Pharmaceutica, Inc., at 2 https://www.dangerousdrugs.us/2009/07/janssen-warned-by-fda-about-misleading-claims.html (last accessed May 4, 2018)

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- "'Significant improvement in social functioning.'"[350]

464. In addition, the September 2, 2004 letter identified "outcome claims [that] are misleading because they imply that patients will experience improved social or physical functioning or improved work productivity when using Duragesic." The claims include "'1,360 loaves . . . and counting,' '[w]ork, uninterrupted,' '[l]ife, uninterrupted,' '[g]ame, uninterrupted,' '[c]hronic pain relief that supports functionality,' '[h]elps patients think less about their pain,' and '[i]mprove[s] . . . physical and social functioning.'" The September 2, 2004 letter stated: "Janssen has not provided references to support these outcome claims. We are not aware of substantial evidence or substantial clinical experience to support these claims."[351]

465. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. Upon information and belief, the advisory noted that the FDA had been "'examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch'" and noted the possibility "that patients and physicians might be unaware of the risks" of using the fentanyl transdermal patch, which is a potent opioid analgesic meant to treat chronic pain that does not respond to other painkillers.[352]

466. Cephalon has been the subject of investigations and enforcement actions for is misrepresentations concerning Actiq. For example:

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[350] *Id*. at 2-3.

[351] *Id*. at 3.

[352] *New Fentanyl Warnings: More Needed to Protect Patients*, Institute for Safe Medication Practices, August 11, 2005; *Safety Warnings Regarding Use of Fentanyl Transdermal (Skin) Patches*, U.S. Food & Drug Administration, July 15, 2005, https://wayback.archive-it.org/7993/20170406013820/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051739.htm.

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467. In October 2000, Cephalon acquired the worldwide product rights to Actiq and began marketing and selling Actiq in the United States. The FDA explicitly stated that Actiq "***must not*** be used in opioid non-tolerant patients," was contraindicated for the management of acute or postoperative pain, could be deadly to children, and was "intended to be used only in the care of opioid-tolerant cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain."[353] The FDA also required that Actiq be provided only in compliance with a strict risk management program that explicitly limited the drug's direct marketing to the approved target audiences, defined as oncologists, pain specialists, their nurses and office staff.[354]

468. Cephalon purchased the rights to Fentora, an even faster-acting tablet formulation of fentanyl, from Cima Labs, and submitted a new drug application to the FDA in August 2005. In September 2006, Cephalon received FDA approval to sell this faster-acting version of Actiq; but once again, concerned about the power and risks inherent to fentanyl, the FDA limited Fentora's approval to the treatment of BTP in cancer patients who were already tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Cephalon began marketing and selling Fentora in October 2006.

469. Due to the FDA's restrictions, Actiq's consumer base was limited, as was its potential for growing revenue. In order to increase its revenue and market share, Cephalon needed to find a broader audience and thus began marketing its lollipop to treat headaches, back pain, sports injuries and other chronic non-cancer pain, targeting non-oncology practices, including, but not

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[353] *Id.*

[354] See John Carreyrou, *Narcotic "Lollipop" Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2006), https://www.wsj.com/articles/SB116252463810112292.

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limited to, pain doctors, general practitioners, migraine clinics, anesthesiologists and sports clinics. It did so in violation of applicable regulations prohibiting the marketing of medications for off-label use and indirect contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

470. Beginning in or about 2003, former Cephalon employees filed four whistleblower lawsuits claiming the company had wrongfully marketed Actiq for unapproved off-label uses. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay $425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil).

According to a DOJ press release, Cephalon trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CME to promote off-label uses.[355]

471. Then-acting U.S. Attorney Laurie Magid commented on the dangers of Cephalon's unlawful practices:

> "This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line. People have an absolute right to their doctors' best medical judgment. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved."[356]

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[355] Press Release, U.S. Department of Justice, Pharmaceutical Company Cephalon To Pay $425 Million For Off-Label Drug Marketing (Sept. 29, 2008), https://wayback.archive-it.org/7993/20170722191120/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm

[356] *Id.*

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472. Upon information and belief, documents uncovered in the government's investigations confirm that Cephalon directly targeted non-oncology practices and pushed its sales representatives to market Actiq for off-label use. For instance, the government's investigations confirmed:

a. Cephalon instructed its sales representatives to ask non-cancer doctors whether they have the potential to treat cancer pain. Even if the doctor answered "no," a decision tree provided by Cephalon instructed the sales representatives to give these physicians free Actiq coupons;

b. Cephalon targeted neurologists in order to encourage them to prescribe Actiq to patients with migraine headaches;

c. Cephalon sales representatives utilized the assistance of outside pain management specialists when visiting non-cancer physicians to pitch Actiq. The pain management specialist would falsely inform the physician that Actiq does not cause patients to experience a "high" and carries a low risk of diversion toward recreational use;

d. Cephalon set sales quotas for its sales and marketing representatives that could not possibly have been met solely by promoting Actiq for its FDA-approved indication;

e. Cephalon promoted the use of higher doses of Actiq than patients required by encouraging prescriptions of the drug to include larger-than-necessary numbers of lozenges with unnecessarily high doses of fentanyl; and

f. Cephalon promoted Actiq for off-label use by funding and controlling CME seminars that promoted and misrepresented the efficacy of the drug for off-label uses such as treating migraine headaches and for patients not already opioid-tolerant.[357]

473. The FDA's letters and safety alerts, the DOJ and state investigations, and the massive settlement seemed to have had little impact on Cephalon as it continued its deceptive marketing strategy for both Actiq and Fentora.

474. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid-tolerant had been

[357] John Carreyrou, Cephalon Used Improper Tactics to Sell Drug, Probe Finds, Wall St. J., Nov. 21, 2006, at B1 (hereinafter "Carreyrou, Cephalon Used Improper Tactics").

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prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: "Fentora should not be used to treat any type of short-term pain."[358]

475. Nevertheless, in 2008, Cephalon pushed forward to expand the target base for Fentora and filed a supplemental drug application requesting FDA approval of Fentora for the treatment of non-cancer BTP. In the application and supporting presentations to the FDA, Cephalon admitted both that it knew the drug was heavily prescribed for off-label use and that the drug's safety for such use had never been clinically evaluated.[359] An FDA advisory committee noted that Fentora's existing risk management program was ineffective and stated that Cephalon would have to institute a risk evaluation and mitigation strategy for the drug before the FDA would consider broader label indications. In response, Cephalon revised Fentora's label and medication guide to add strengthened warnings.

476. But in 2009, the FDA once again informed Cephalon that the risk management program was not sufficient to ensure the safe use of Fentora for already approved indications.

477. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient

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[358] Press Release, U.S. Food & Drug Administration, Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept. 26, 2007), https://wayback.archive-it.org/7993/20170722191120/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm

[359] *FENTORA (fentanyl buccal tablet) CII, Joint Meeting of Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committee*, U.S. Food & Drug Administration (May 6, 2008), https://wayback.archive-it.org/7993/20170405034338/https://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356oph2-02-VanZee_files/frame.htm

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with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case."[360] Rather, Fentora was only indicated for those who were already opioid tolerant. It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

478. Flagrantly disregarding the FDA's refusal to approve Fentora for non-cancer BTP and its warning against marketing the drug for the same, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq.

479. The misrepresentations disseminated by members of the Opioid Marketing Enterprise, and the RICO Marketing Defendants, caused Plaintiff and Oregon consumers to pay for excessive opioid prescriptions, suffer injuries and losses, and to incur costs associated with the opioid epidemic caused by the Opioid Marketing Enterprise.

480. The RICO Marketing Defendants alone could not have accomplished the purpose of the Opioid Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as "neutral" and more "scientific" than the RICO Marketing Defendants themselves. Without these misrepresentations, the Opioid Marketing Enterprise could not have achieved its common purpose.

481. The impact of the Opioid Marketing Enterprise's scheme is still in place – i.e., the opioids continue to be prescribed and used for chronic pain throughout the State of Oregon, and the epidemic continues to injury Plaintiff, and consume the resources of Plaintiff's and Oregon's health care and law enforcement systems.

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[360] Letter from Michael Sauers, Regulatory Review Officer, Division of Drug Marketing, Advertising and Communications, to Carole S. Marchione, Senior Director and Group Leader, Regulatory Affairs (March 26, 2009)

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482. The foregoing evidences that the RICO Marketing Defendants, the Front Groups, and the KOLs were each willing participants in the Opioid Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

B. CONDUCT OF THE OPIOID MARKETING ENTERPRISE.

483. During time period described in this Complaint, from approximately the late 1990s to the present, the RICO Marketing Defendants exerted control over the Opioid Marketing Enterprise and participated in the operation or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. Creating a body of deceptive, misleading and unsupported medical and popular literature, electronic and print advertisements, sales and promotional training materials, and CMEs and speaker presentations, about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to be relied upon by physicians, patients, and payors;

b. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;

c. Providing substantial opportunities for KOLs to participate in research studies on topics the RICO Marketing Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

e. Paying KOLs to serve as consultants or on the RICO Marketing Defendants' advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically over meals or at conferences;

f. Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;

g. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the RICO Marketing Defendants suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

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h. Paying significant amounts of money to the leaders and individuals associated with Front Groups;

i. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;

j. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

k. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

l. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;

m. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the RICO Marketing Defendants, such as veterans and the elderly, and then funded that distribution;

n. Concealing their relationship to and control of Front Groups and KOLs from the Plaintiff and the public at large; and

o. Intending that Front Groups and KOLs would distribute through the mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

484. The Front Groups also participated in the conduct of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the RICO Marketing Defendants' messages;

b. The Front Groups distributed, through the mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;

d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

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e. The Front Groups strongly criticized the 2016 guidelines from the CDC that recommended limits on opioid prescriptions for chronic pain; and

f. The Front Groups concealed their connections to the KOLs and the RICO Marketing Defendants.

485. The RICO Marketing Defendants' Front Groups, "with their large numbers and credibility with policymakers and the public—have 'extensive influence in specific disease areas.'" The RICO Marketing Defendants' larger Front Groups "likely have a substantial effect on policies relevant to their industry sponsors."[361] "By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."[362]

486. Upon information and belief, the KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the RICO Marketing Defendants' messages themselves;

b. The KOLs distributed, through the mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;

d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The KOLs strongly criticized the 2016 guidelines from the CDC that recommended limits on opioid prescriptions for chronic pain; and

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[361] *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members' Office, February 12, 2018 https://www.hsdl.org/?abstract&did=808171 ("*Fueling an Epidemic*"), at 1.

[362] *Id.* 2.

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f. The KOLs concealed their connections to the Front Groups and the RICO Marketing Defendants, and their sponsorship by the RICO Marketing Defendants.

487. The scheme devised and implemented by the RICO Marketing Defendants and members of the Opioid Marketing Enterprise, amounted to a common course of conduct intended to increase the RICO Marketing Defendants sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

C. PATTERN OF RACKETEERING ACTIVITY

488. The RICO Marketing Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and interstate wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

489. The RICO Marketing Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Marketing Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Marketing Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Marketing Enterprise, the mail and interstate wire facilities. The RICO Marketing Defendants participated in the scheme to defraud by using mail, telephones and the Internet to transmit mailings and wires in interstate or foreign commerce.

490. The pattern of racketeering activity described herein used by the RICO Marketing Defendants and the Opioid Marketing Enterprise likely involved thousands of separate instances

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of the use of the mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including virtually uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain, with the goal of profiting from increased sales of the RICO Marketing Defendants' drugs induced by consumers, prescribers, regulators and Plaintiff's reliance on the RICO Marketing Defendants' misrepresentations.

491. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which Defendants, the Front Groups and the KOLs defrauded and intended to defraud Oregon consumers, Plaintiff, and other intended victims.

492. In devising and executing the illegal scheme, the RICO Marketing Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute and non-cancer pain. The RICO Marketing Defendants and members of the Opioid Marketing Enterprise knew that these representations violated the FDA approved use these drugs, and were not supported by actual evidence. For the purpose of executing the illegal scheme, the RICO Marketing Defendants intended that that their common purpose and scheme to defraud would, and did, use mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance their illegal scheme.

493. The RICO Marketing Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or

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commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

494. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Oregon consumers, prescribers, regulators and Plaintiff. The RICO Marketing Defendants, Front Groups and KOLs calculated and intentionally crafted the scheme and common purpose of the Opioid Marketing Enterprise to ensure their own profits remained high. In designing and implementing the scheme, the RICO Marketing Defendants understood and intended that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the RICO Marketing Defendants' products.

495. By intentionally misrepresenting the risks and benefits of using opioids for chronic pain, and then subsequently failing to disclose such practices to Oregon consumers, prescribers, regulators and Plaintiff, RICO Marketing Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

496. The racketeering activities conducted by the RICO Marketing Defendants, Front Groups and KOLs amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Oregon consumers, prescribers, regulators and Plaintiff. Each separate use of the mail and/or interstate wire facilities employed by Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results

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affecting the same victims, including Oregon consumers, prescribers, regulators and Plaintiff. The RICO Marketing Defendants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Opioid Marketing Enterprise.

497. The RICO Marketing Defendants' pattern of racketeering activity alleged herein and the Opioid Marketing Enterprise are separate and distinct from each other. Likewise, the RICO Marketing Defendants are distinct from the Opioid Marketing Enterprise.

498. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

499. Many of the precise dates of the Opioid Marketing Enterprise's uses of the mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by the RICO Marketing Defendants, Front Groups, and KOLs. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise alleged herein depended upon secrecy. However, Plaintiff has described the occasions on which the RICO Marketing Defendants, Front Groups, and KOLs disseminated misrepresentations and false statements to Oregon consumers, prescribers, regulators and Plaintiff, and how those acts were in furtherance of the scheme, and do so further below.

500. The RICO Marketing Defendants' use of the mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, *inter alia*:

a. Marketing materials about opioids, and their risks and benefits, which the RICO Marketing Defendants sent to health care providers, transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country and the State;

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b. Written representations and telephone calls between the RICO Marketing Defendants and Front Groups and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

c. E-mails, telephone and written communications between the RICO Marketing Defendants and the Front Groups and KOLs agreeing to or implementing the opioids marketing scheme;

d. Communications between the RICO Marketing Defendants, Front Groups, KOLs, and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

e. Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout the State that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and

f. Receipts of increased profits sent through the mail and interstate wire facilities – the wrongful proceeds of the scheme.

501. In addition to the above-referenced predicate acts, it was foreseeable to the RICO Marketing Defendants that the Front Groups and the KOLs would distribute publications through the mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

502. The RICO Marketing Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

503. To achieve the common goal and purpose of the Opioid Marketing Enterprise, the RICO Marketing Defendants and members of the Opioid Marketing Enterprise hid from the consumers, prescribers, regulators and Plaintiff: (1) the fraudulent nature of the RICO Marketing Defendants' marketing scheme; (2) the fraudulent nature of statements made by the RICO Marketing Defendants and by their KOLs, Front Groups and other third parties regarding the safety

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and efficacy of prescription opioids; and (3) the true nature of the relationship between the members of the Opioid Marketing Enterprise.

504. The RICO Marketing Defendants, and each member of the Opioid Marketing Enterprise agreed, with knowledge and intent, to the overall objective of the RICO Marketing Defendants' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

505. Indeed, for the RICO Marketing Defendants' fraudulent scheme to work, each of the RICO Marketing Defendants had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the RICO Marketing Defendants each financed, supported, and worked through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines.

506. As described herein, the RICO Marketing Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

507. The RICO Marketing Defendants predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Marketing Defendants. The predicate acts were committed or caused to be committed by the RICO Marketing Defendants through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

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508. The RICO Marketing Defendants' predicate acts and pattern of racketeering activity were a substantial and foreseeable cause of Plaintiff's injury and the relationship between the RICO Marketing Defendants' conduct and Plaintiff's injury is logical and not speculative. It was foreseeable to the RICO Marketing Defendants that when they fraudulently marketed highly-addictive and dangerous drugs, that were approved for very limited and specific uses by the FDA, as non-addictive and safe for off-label uses such as moderate pain, non-cancer pain, and long-term chronic pain, that the RICO Marketing Defendants would create an opioid-addiction epidemic that logically, substantially and foreseeably harmed Plaintiff.

509. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

D. DAMAGES.

1. Impact of the Opioid Marketing Enterprise.

510. Plaintiff has suffered damages as described in paragraphs 67-87 above.

2. Relief Sought.

511. The RICO Marketing Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in their business and property. The RICO Marketing Defendants' pattern of racketeering activity logically, substantially and foreseeably caused an opioid epidemic. Plaintiff's injuries, as described below, were not unexpected, unforeseen or independent.[363] Rather, as Plaintiff allege, the RICO Marketing Defendants knew

[363] *Traveler's Property Casualty Company of America v. Actavis, Inc.*, 225 Cal. Rptr. 3d 5, 19 (Cal. Ct. App. 2017).

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that the opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse.[364] Nevertheless, the RICO Marketing Defendants engaged in a scheme of deception, that utilized the mail and interstate wires as part of their fraud, in order to increase sales of their opioid products.

512. It was foreseeable and expected that a massive marketing campaign utilized by the RICO Marketing Defendants that misrepresented the non-addictive and effective use of prescription opioids for purposes for which they are not suited and not approved by the FDA would lead to a nationwide opioid epidemic.[365] It was also foreseeable and expected that the RICO Marketing Defendants' marketing campaign would lead to increased opioid addiction and overdose.[366] Plaintiff's injury were logically, foreseeable, and substantially caused by the opioid epidemic that the RICO Marketing Defendants created.

513. Specifically, the RICO Marketing Defendants' predicate acts and pattern of racketeering activity caused the opioid epidemic which has injured Plaintiff in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic. Plaintiff's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a. Losses caused by purchasing and/or paying reimbursements for the RICO Marketing Defendants' prescription opioids, that Plaintiff would not have paid for or purchased but for the RICO Marketing Defendants' conduct;

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[364] *Id.*

[365] *Id.*

[366] *Id.*

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b. Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

c. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

d. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;

e. Costs associated with providing police officers, firefighters, and emergency and/or first responders with Naloxone – an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

f. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

g. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families; and

h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population.

514. Plaintiff's injuries were proximately caused by the RICO Marketing Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiff's injuries. But for the opioid-addiction epidemic created by the RICO Marketing Defendants' conduct, Plaintiff would not have lost money or property.

515. Plaintiff's injuries were directly caused by the RICO Marketing Defendants' pattern of racketeering activities.

516. Plaintiff is the most directly harmed entity and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

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517. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT III

RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT
18 U.S.C. § 1961 *et seq.*
(Against Defendants Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal and AmerisourceBergen)
(The "Opioid Diversion Enterprise")

518. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

519. Plaintiff brings this Claim against the following Defendants, as defined above: Purdue, Cephalon, Endo, Mallinckrodt, Actavis (the "Manufacturer Defendants"), McKesson, Cardinal, and AmerisourceBergen (the "Distributor Defendants") (collectively, for purposes of this Claim, the "RICO Diversion Defendants").

520. The RICO Diversion Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise as defined in 18 U.S.C. § 1961(4). Alternatively, the RICO Diversion Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4). Specifically, each of the RICO Diversion Defendants was a member of the Healthcare Distribution Alliance (the "HDA"),[367] which is a distinct legal entity that satisfies the definition of a RICO enterprise because it is a non-profit corporation and, therefore, and "enterprise" within the definition set out in 18 U.S.C. § 1961(4). Upon information and belief, each of the RICO Diversion

[367] Health Distribution Alliance, History, Health Distribution Alliance, (last visited Sept. 15, 2017), https://www.healthcaredistribution.org/about/hda-history.

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Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to this cause of action. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the "Opioid Diversion Enterprise."

521. For over a decade, the RICO Diversion Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Diversion Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. As "registrants" under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the "CSA"), the RICO Diversion Defendants operated and continue to operate within a "closed-system." The CSA restricts the RICO Diversion Defendants' ability to manufacture or distribute Schedule II substances like opioids by: (1) requiring them to make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids; (2) register to manufacture or distribute opioids; (3) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; and (4) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

522. The closed-system created by the CSA, and the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids

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from "legitimate channels of trade" to the illicit market by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances]."[368]

523. Finding it impossible to legally achieve their ever-increasing sales ambitions, members of the Opioid Diversion Enterprise (defined below) engaged in the common purpose of fraudulently increasing the quotas that governed the manufacture and distribution of their prescription opioids. The RICO Diversion Defendants formed and pursued their common purpose through the many personal interactions that they had, confidentially, in organizations like the Pain Care Forum and the Healthcare Distribution Alliance.

524. The RICO Diversion Defendants' common purpose and fraudulent scheme to unlawfully increase the DEA quotas violated the RICO Act in two ways. First, the RICO Diversion Defendants violated the RICO Act because they engaged in the felonious manufacture, buying selling, or otherwise dealing in controlled substances that are punishable by law in the United States. Specifically, the RICO Diversion Defendants "furnish[ed] false or fraudulent material information in, or omit[ted] material information from, applications, reports, records, and other document required to be made, kept, and filed under 21 U.S.C. §§ 801, et seq.", in violation of 21 U.S.C. § 843(b), which is a felony. Second, the RICO Diversion Defendants violated the RICO Act by engaging in mail and wire fraud. The RICO Diversion Defendants' common purpose and fraudulent scheme was intended to, and did, utilize mail and interstate wire facilities for the commission of their fraud in violation 18 U.S.C. §§ 1341 (mail fraud) and 1343 (wire fraud).

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[368] See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4572; see also Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015, available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf (stating that "[w]hen Congress passed the CSA, the quota system was intended to reduce or eliminate diversion from 'legitimate channels of trade'").

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525. The RICO Diversion Defendants' fraudulent scheme arises at the intersection between the quotas governing the RICO Diversion Defendants' prescription opioids and the RICO Diversion Defendants' duty to identify, report, and halt suspicious orders of controlled substances. The RICO Diversion Defendants' formed an enterprise with the intent to fraudulently increase the quotas for prescription opioids by refusing to identify, report and halt suspicious orders, thereby omitting both the fact and the RICO Diversion Defendants' knowledge of widespread diversion of prescription opioids into illegitimate channels.

526. The RICO Diversion Defendants engaged in systematic and fraudulent acts as part of the Opioid Diversion Enterprise, that furnished false or fraudulent material information in, and omitted material information from their applications, reports, records and other documents that the RICO Diversion Defendants were required to make, keep and/or file. Furthermore, the RICO Diversion Defendants engaged in systematic and fraudulent acts as part of the Opioid Diversion Enterprise that were intended to and actually did utilize the mail and interstate wire facilities of the United States, including refusing to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders.[369]

527. Through the RICO Diversion Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly requested increases of the quotas governing the manufacture, sale and distribution of prescription opioids, misrepresented that they were complying with their duties under the CSA, furnished false or fraudulent material information in, and omitted material information from their applications, reports, records and other documents, engaged in unlawful

[369] 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

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sales of painkillers that resulted in diversion of controlled substances through suspicious orders, and refused to identify or report suspicious orders of controlled substances sales to the DEA.[370] Defendants' refusal to report suspicious orders resulted in artificial and illegal increases in the annual production quotas for opioids allowed by the DEA. The end result of the RICO Diversion Defendants' fraudulent scheme and common purpose was continually increasing quotas that generated obscene profits and, in turn, fueled an opioid epidemic.

528. The RICO Diversion Defendants' illegal scheme was hatched by an enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed in perfect harmony by each of them. In particular, each of the RICO Diversion Defendants were associated with, and conducted or participated in, the affairs of the Opioid Diversion Enterprise, whose common purpose was fraudulently increase the quotas governing the manufacture and sale of prescription opioids.

529. The success of the RICO Diversion Defendants' scheme allowed them to unlawfully increase and/or maintain high production quotas and, as a direct result, allowed them to make billions from the unlawful sale and diversion of opioids.

530. Simultaneously, the opioid epidemic created by the RICO Diversion Defendants' actions caused Plaintiff's injuries. Plaintiff's injuries were and are a reasonably foreseeable consequence of the prescription opioid addiction epidemic that the RICO Diversion Defendants created by fraudulently increasing quotas, misrepresenting their compliance with their duties under the CSA, and allowing the widespread diversion of legally produced prescription opioids into the

[370] 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

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illicit market. As explained in detail below, the RICO Diversion Defendants' misconduct violated Section 1962(c) and Plaintiff is entitled to treble damages for its injuries under 18 U.S.C. § 1964(c).

A. THE OPIOID DIVERSION ENTERPRISE.

531. Recognizing that there is a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act ("CSA") in 1970.[371] The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals.[372] Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.[373] Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market."[374] Moreover, "[t]he closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain."[375] All registrants—manufacturers and distributors alike—must

[371] Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

[372] *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.

[373] *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(20; 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

[374] See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015, available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf.

[375] See Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012, available at https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf.

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adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion.[376] When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse.[377] The result is the scourge of addiction that has occurred.

532. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs."[378] When evaluating production quotas, the DEA was instructed to consider the following information:

a. Information provided by the Department of Health and Human Services;

b. Total net disposal of the basic class by all manufacturers;

c. Trends in the national rate of disposal of the basic class;

d. An applicant's production cycle and current inventory position;

e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and

f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical

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[376] *Id.*

[377] Joseph T. Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

[378] See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4572; see also Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015, available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf (stating that "[w]hen Congress passed the CSA, the quota system was intended to reduce or eliminate diversion from 'legitimate channels of trade'").

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> availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.[379]

533. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.[380]

534. At all relevant times, the RICO Diversion Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute. In support of this common purpose and fraudulent scheme, the RICO Diversion Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas. The RICO Diversion Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

535. The opioid epidemic has its origins in the mid-1990s, and between 1997 and 2007, per capita purchase of methadone, hydrocodone, and oxycodone increased 13-fold, 4-fold, and 9-fold, respectively. Upon information and belief, the Opioid Diversion Enterprise has been ongoing for at least the last decade.[381]

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[379] *See* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015, available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf.

[380] *Id.* (citing 21 U.S.C. 842(b)).

[381] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (last visited Sept. 19, 2017),

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536. The Opioid Diversion Enterprise was and is a shockingly successful endeavor. The Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis. However, it was not until recently that federal and state regulators finally began to unravel the extent of the enterprise and the toll that it exacted on the American public.

537. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each RICO Diversion Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Diversion Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Diversion Defendants; (d) was characterized by interpersonal relationships among the RICO Diversion Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and resulting sales.

538. The Opioid Diversion Enterprise also engaged in efforts to constrain the DEA's authority to hold the RICO Diversion Defendants liable for disregarding their duty to prevent diversion. Members of the Pain Care Forum (described in greater detail below) and the Healthcare Distribution Alliance lobbied for the passage of legislation to weaken the DEA's enforcement authority. To this end, the Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke

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https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic.

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registrations.[382] The HDA and other members of the Pain Care Forum contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees and political parties. Upon information and belief, the Pain Care Forum and its members and HDA, poured millions into such efforts.

539. The RICO Diversion Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity that involves a fraudulent scheme to profit from the unlawful sale of prescription opioids by increasing the quotas governing the manufacture and sale of these controlled substances. In order to achieve that goal, the RICO Diversion Defendants knowingly allowed suspicious orders of controlled substances to occur unhindered while millions of opioid doses diverted into illegal markets. The end result of this strategy was exactly as the RICO Diversion Defendants intended – artificially increased quotas for the manufacture and distribution of opioids, all of which resulted in a national opioid epidemic.

540. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such

[382] *See* HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

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as manufacture, sale, distribution, and shipment of prescription opioids throughout the United States, and the corresponding payment and/or receipt of money from such interstate sales.

541. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the RICO Diversion Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

542. Each of the RICO Diversion Defendants had systematic links to each other through joint participation in trade industry organizations, contractual relationships and continuing coordination of activities. The RICO Diversion Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the RICO Diversion Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

543. The RICO Diversion Defendants exerted substantial control over the Opioid Diversion Enterprise through their membership in the Pain Care Forum, the HDA, and through their contractual relationships.

544. The Pain Care Forum has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

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545. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[383] Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[384]

546. Not surprisingly, each of the RICO Diversion Defendants who stood to profit from expanded prescription opioid use is a member of and/or participant in the PCF.[385] In 2012, membership and participating organizations included the HDA (of which all RICO Marketing Defendants are members), Endo, Purdue, Actavis (i.e., Allergan), and Teva (the parent company of Cephalon).[386] Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.[387] Upon information and belief, the Distributor Defendants participated directly in the PCF as well.

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[383] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic (emphasis added).

[384] *Id*.

[385] PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf.

[386] *Id*. Upon information and belief, Mallinckrodt became an active member of the PCF sometime after 2012.

[387] *Id*. The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Medical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Sourcing for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. Executive Committee,

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547. Additionally, the HDA led to the formation of interpersonal relationships and an organization between the RICO Diversion Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis (i.e., Allergan), Endo, Purdue, Mallinckrodt and Cephalon were members of the HDA.[388] Additionally, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Manufacturer Defendants by advocating for the many benefits of members, including "**strengthen[ing] . . . alliances**."[389]

548. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[390] Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and "alliances" between the Manufacturer Defendants and Distributor Defendants.

Healthcare Distribution Alliance (last visited Apr. 24, 2018), https://www.healthcaredistribution.org/about/executive-committee.

[388] Manufacturer Membership, Healthcare Distribution Alliance, (last visited Sept. 14, 2017), https://www.healthcaredistribution.org/about/membership/manufacturer.

[389] Manufacturer Membership Benefits, Healthcare Distribution Alliance, (last visited Sept. 14, 2017), https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en.

[390] *Id.*

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549. The application for manufacturer membership in the HDA further indicates the level of connection between the RICO Diversion Defendants and the level of insight that they had into each other's businesses.[391] For example, the manufacturer membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

550. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information.

551. And, manufacturers were asked to identify their "most recent year end net sales" through wholesale distributors, including the Distributor Defendants AmerisourceBergen, Cardinal Health, and McKesson and their subsidiaries.

552. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

553. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA, and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[392] The conferences also gave the Manufacturer and Distributor Defendants

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[391] Manufacturer Membership Application, Healthcare Distribution Alliance, (last visited Sept. 14, 2017), https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-application.ashx?la=en.

[392] Business and Leadership Conference – Information for Manufacturers, Healthcare Distribution Alliance. https://web.archive.org/web/20160109102639/http://www.healthcaredistribution.org:80/events/2016-business-and-leadership-conference/blc-for-manufacturers (last visited May 4, 2018).

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"unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[393] The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. It is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.[394]

554. Third, the RICO Diversion Defendants maintained their interpersonal relationships by working together, through contractual chargeback arrangements, to exchanging sales information and drive the unlawful sales of their opioids. To this end, the Manufacturer Defendants engaged in an industry-wide practice of paying rebates to the Distributor Defendants for sales of prescription opioids.[395]

555. For example, the *Washington Post* reported that "[o]n Aug. 23, 2011, DEA supervisors met with Mallinckrodt executives at the agency's headquarters in Arlington, Va., the day a rare 5.8-magnitude earthquake hit the Washington region. People involved in the case still call the gathering 'the earthquake meeting.' DEA officials showed the company the remarkable amounts of its oxycodone going to distributors and the number of arrests being made for

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[393] *Id*.

[394] 2015 Distribution Management Conference and Expo, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-distribution-management-conference (last visited Sept. 14, 2017).

[395] Lenny Bernstein & Scott Higham, *The government's struggle to hold opioid manufacturers accountable*, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356; *see also*, Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png; Letters From Sen. Claire McCaskill, (March 28, 2017), https://www.mccaskill.senate.gov/opioid-investigation; Purdue Managed Markets, Purdue Pharma, (last visited Sept. 14, 2017), http://www.purduepharma.com/payers/managed-markets/.

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oxycodone possession and distribution on the street, according to one participant in the meeting who also spoke on the condition of anonymity because the case is pending."[396]

556. "Three weeks after the Aug. 23 meeting, Mallinckrodt notified 43 of its distributors that they would no longer receive rebates from the company if they continued to supply certain pharmacies whose orders appeared to be suspicious."[397]

557. "On Nov. 30, 2011, the DEA served a subpoena on Mallinckrodt, demanding documents related to its suspicious-order-monitoring program, according to the company's filings with the Securities and Exchange Commission. The subpoena brought a windfall of information. The DEA gained access to data from Mallinckrodt's rebate or 'chargeback' program, an industry-wide practice that provides reimbursements to wholesale distributors. That information and other records showed where Mallinckrodt's oxycodone was going — from the company to its network of distributors to retailers down the chain."[398]

558. In addition, the Distributor Defendants and Manufacturer Defendants participated, through the HDA, in webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.[399] For example, on April 27, 2011, the HDA offered a webinar to

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[396] Lenny Bernstein & Scott Higham, *The government's struggle to hold opioid manufacturers accountable*, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356

[397] *Id.*

[398] *Id.*

[399] Webinars, Healthcare Distribution Alliance, (last visited Sept. 14, 2017), https://www.healthcaredistribution.org/resources/webinar-leveraging-edi.

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"accurately and efficiently exchange business transactions . . . between distributors and manufacturers . . . ":

Webinar Leveraging EDI: Order-to-Cash Transactions CD Box Set

(Webinar held: April 27, 2011) Using EDI to accurately and efficiently exchange business transactions (i.e., purchase orders, acknowledgements, ship notices, invoices, etc.) between distributors and manufacturers in the healthcare supply chain is critical. The development and use of voluntary guidelines for specific EDI standards provide industry trading partners with a means to effectively convey the necessary information.

Hear updates on HDMA's Order-to-Cash Guidelines for Electronic Data Interchange (EDI) in the Healthcare Product Supply Chain, including the 810 Invoice; 850 Purchase Order; 855 Purchase Order Acknowledgement; and the 856 Ship Notice/Manifest.

559. On information and belief, the Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

560. And, through the HDA, manufacturers were asked to identify their "most recent year end net sales" through wholesale distributors, including the Distributor Defendants as follows:

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Company	Most Recent Year End Net Sales
Henry Schein, Inc.	
Henry Schein Distribution Centers (7)	
Hospital Pharmaceutical Consulting (1)	
KeySource Medical, Inc. (1)	
Louisiana Wholesale Drug Co. Inc. (1)	
McKesson Corporation (71)	
McKesson Supply Solutions (25)	
McKesson Canada (12)	
McKesson Corporation (4)	
McKesson Specialty Health (1)	
McKesson Strategic Redistribution Center (1)	
McKesson Medical Surgical (1)	
Physician Sales & Service (PSS) (25)	
US Oncology (1)	
DeVictoria Healthcare, Inc. PR (1)	
Miami-Luken, Inc. (1)	
Morris & Dickson Co., LLC (1)	
Mutual Wholesale Drug Co. (1)	
PBA Health (1)	
Prescription Supply, Inc. (1)	
Prodigy Health Supplier Corporation (1)	
Quality Care Products, LLC (1)	
RDC (3)	
R&S Northeast LLC (2)	
Richie Pharmacal Co., LLC (1)	
Seacoast Medical LLC (1)	
Smith Drug Company, Div. JM Smith Corporation (4)	
Burlington Drug Company, Inc. (1)	
Smith Drug Company, Div. JM Smith Corporation (3)	
Top Rx (4)	
Value Drug Company (1)	
VaxServe (1)	
TOTAL SALES (millions)	$ 0

561. The contractual relationships among the RICO Diversion Defendants also include vault security programs. The RICO Diversion Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. Upon information and belief, the manufacturers negotiated agreements whereby the manufacturers installed security vaults for distributors in exchange for agreements to maintain minimum sales performance thresholds. Upon information and belief, these agreements were used by the RICO Diversion Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

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562. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The RICO Diversion Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrate that the leaders of each of the RICO Diversion Defendants were in communication and cooperation.

563. Alternatively, the RICO Diversion Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Diversion Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. As alleged, the HDA[400] is a distinct legal entity that satisfies the definition of a RICO enterprise because it is a corporation formed under the laws of the District of Columbia, doing business in Virginia. As such, the HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4).

564. On information and belief, each of the RICO Diversion Defendants is a member, participant, and/or sponsor of the HDA, and has been since at least 2006, and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

[400] Health Distribution Alliance, History, Health Distribution Alliance, (last visited Sept. 15, 2017), https://www.healthcaredistribution.org/about/hda-history.

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565. Each of the RICO Diversion Defendants is a legal entity separate and distinct from the HDA. Additionally, the HDA serves the interests of distributors and manufacturers beyond the RICO Diversion Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the RICO Diversion Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE.

566. During the time period alleged in this Complaint, the RICO Diversion Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:

567. Defendants disseminated false and misleading statements to state and federal regulators claiming that (1) the quotas for prescription opioids should be increased; (2) they were complying with their obligations to maintain effective controls against diversion of their prescription opioids; (3) they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids; (4) they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and (5) they did not have the capability to identify suspicious orders of controlled substances despite their possession of national, regional, state, and local prescriber- and patient-level data that allowed them to track prescribing patterns over time, which the Defendants obtained from data companies, including but not limited to: IMS Health, QuintilesIMS, Iqvia, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services,

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Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the "Data Vendors").

568. The RICO Diversion Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[401]

569. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the RICO Diversion Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[402] Upon information and belief, the "know your customer" questionnaires informed the RICO Diversion Defendants of the number of pills that the pharmacies

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[401] *See* HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

[402] Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration, https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr., Kathleen H. Dooley, Esq. Pharmaceutical Production Diversion: Beyond the PDMA, Purdue Pharma and McGuireWoods LLC, https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

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sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

570. The RICO Diversion Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors' information purchased by the RICO Diversion Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.[403]

571. IMS, for example, provided the RICO Diversion Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.[404]

[403] A Verispan representative testified that the RICO Diversion Defendants use the prescribing information to "drive market share." Brief for Petitioners, *Sorrell v. IMS Health Inc.*, 2011 WL 661712, *9-10 (Feb. 22, 2011).

[404] Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How we Turned a Mountain of Data into a Few Information-rich Molehills*, Figure 2 at p. 3 (last visited Feb. 15, 2018), http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&type=pdf.

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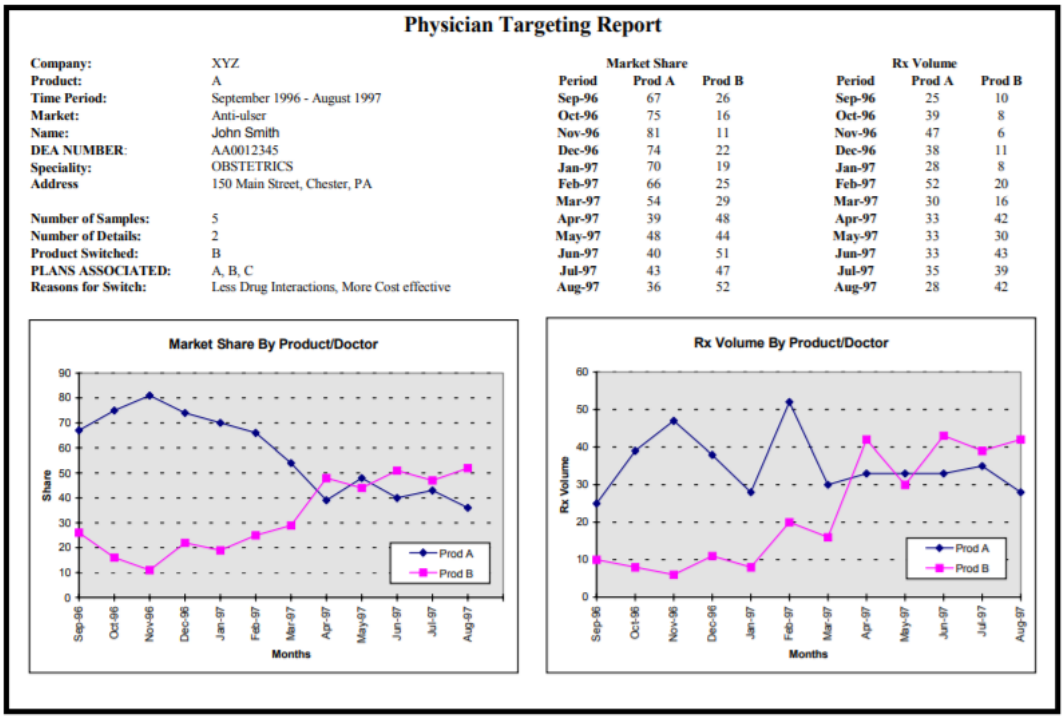
Figure 2:



Physician Targeting Report

Company:	XYZ
Product:	A
Time Period:	September 1996 - August 1997
Market:	Anti-ulser
Name:	John Smith
DEA NUMBER:	AA0012345
Speciality:	OBSTETRICS
Address	150 Main Street, Chester, PA
Number of Samples:	5
Number of Details:	2
Product Switched:	B
PLANS ASSOCIATED:	A, B, C
Reasons for Switch:	Less Drug Interactions, More Cost effective

Market Share

Period	Prod A	Prod B
Sep-96	67	26
Oct-96	75	16
Nov-96	81	11
Dec-96	74	22
Jan-97	70	19
Feb-97	66	25
Mar-97	54	29
Apr-97	39	48
May-97	48	44
Jun-97	40	51
Jul-97	43	47
Aug-97	36	52

Rx Volume

Period	Prod A	Prod B
Sep-96	25	10
Oct-96	39	8
Nov-96	47	6
Dec-96	38	11
Jan-97	28	8
Feb-97	52	20
Mar-97	30	16
Apr-97	33	42
May-97	33	30
Jun-97	33	43
Jul-97	35	39
Aug-97	28	42

572. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the RICO Diversion Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.[405]

[405] Joint Appendix, Vol. II, *Sorrell v. IMS Health Inc.*, 2011 WL 705207, *467-471 (Feb. 22, 2011).

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1. The Prescriber Roster shows Prescriber demographics, prescribing information and indicator arrows

Territory : 1102				Weekly Prescriber TR			
Prescriber	Trend	Specialty	Product	WEEK Feb-03-06	WEEK Jan-27-06	WEEK Jan-20-06	WEEK Jan-13-06
Territory : 1102 – TOTAL			PRODUCT A	46	64	58	88
			PRODUCT B	292	253	247	278
			PRODUCT C	55	56	56	58
			PRODUCT D	36	28	34	33
			PRODUCT E	7	9	2	9
			PRODUCT F	1	3	5	0
Doctor A		IM	PRODUCT A	4	1	1	1
			PRODUCT B	2	2	2	3
			PRODUCT C	0	2	0	0
			PRODUCT D	0	0	0	0
			PRODUCT E	0	0	0	0
			PRODUCT F	0	0	0	0
Doctor B		GE	PRODUCT A	3	1	1	2
			PRODUCT B	5	4	7	2
			PRODUCT C	0	1	0	0
			PRODUCT D	0	0	0	0
			PRODUCT E	0	1	0	1
			PRODUCT F	0	0	0	0
Doctor C		GE	PRODUCT A	3	1	2	0
			PRODUCT B	4	5	0	3
			PRODUCT C	0	1	1	0
			PRODUCT D	0	1	0	2
			PRODUCT E	0	0	0	0
			PRODUCT F	0	0	0	0

* * *

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3. Territory Summary Report shows Prescriber Roster information aggregated at a territory level

Territory Summary

Name	Spec	Zip	Product A NRX	Product A MM Share	Product A Rank	Market NRX	Market Rank
ABNEY, RAY C.	P	05302	6	10.7%	43	56	38
ALLISTER, ROBERT	P	03820	6	18.8%	43	32	63
ALTMAN, LEE S.	P	01655	34	14.0%	3	247	3
BALLARD, HARLOW	P	05801	0	0.0%	93	8	96
BARNEY, CHRISTINE A.	P	03766	6	26.1%	43	23	85
BARTON, GAIL	P	03755	13	32.5%	18	40	50
BERNSTEIN, RICHARD A.	P	05401	0	0.0%	93	14	94
BOHNERI, MICHAEL	P	03060	3	4.5%	73	66	29
BOSTIC, JEFFERY O.	CHP	03079	5	10.9%	55	45	44
BREITHOLTZ, TIMOTHY	P	03870	13	34.2%	18	38	52
BROWN, KENNETH	P	03941	4	10.0%	61	40	50
BUCHANAN, KEVIN	P	05701	5	16.1%	55	31	70
CARMAN, MEGAN W.	P	03246	10	12.3%	28	81	18
CARSEN, MARJORIA	P	05701	6	18.2%	43	33	59
CATPANO-FRIEDMAN, LISA	P	05201	5	8.6%	43	70	25
CLARKE-RUBIN, LORNA	P	12901	8	24.2%	32	33	59
COHEN, DEVRA H.	CHP	03060	3	6.5%	73	46	44
COLE, STEPHEN A.	P	05101	5	13.2%	55	38	52
COTTON, PAUL G.	P	05401	13	28.3%	18	46	44
CUSI, PRISCILLA M.	P	03104	17	7.9%	14	215	5
DAVISON, MARTHA F.	P	03110	14	11.3%	16	124	8
DEJONG, JACOB	P	03067	0	0.0%	93	21	87
DELFAUSSE, PETER O.	P	03301	6	35.3%	43	17	90
DENNETT, DOUGLAS E.	CHP	05401	0	0.0%	93	33	59
DEPPE, SUSAN L.	P	05401	1	0.3%	87	300	2
DEVENDERRAO, T.	P	03060	7	9.6%	37	73	21

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573. This information allowed the RICO Diversion Defendants to track and identify instances of, overprescribing.[406] In fact, one of the Data Venders' experts testified that a

[406] *See* Brief of Respondents IMS Health Inc., Verispan, LLC, and Source Healthcare Analytics, Inc., *Sorrell v. IMS Health Inc.*, 2011 WL 1149043, *37-38 (March 24, 2011) (arguing that data had been used to . "identify overuse of antibiotics in children," and "whether there is a wide use of anthrax prophylactic medicines after the scares that happened in 2001."). The Data Vender Respondents also cited evidence from the trial court proving that "because analysis of PI data makes it possible to 'identify overuse of a pharmaceutical in specific populations,' the government employs the 'data to monitor usage of controlled substances.'" *Id.*

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manufacturer of "narcotic analgesics" used the Data Venders' information to track, identify, report and halt suspicious orders of controlled substances.[407]

> [455] Q. Besides marketing and promotion, are there any other uses for prescriber-identifiable data?
>
> A. There's a number of other uses.
>
> Q. And what are those?
>
> A. The one that I was most impressed with was a firm that used it to identify – a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product and they would use that to notify the DEA and other authorities of potential problems.

574. The RICO Diversion Defendants were, therefore, collectively aware of the suspicious orders that flowed daily from their manufacturing and distribution facilities.

575. The RICO Diversion Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. The RICO Diversion Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178

[407] *Id*. at *38. Eugene "Mick" Kolassa testified as an expert on behalf of the Data Vender stating that "a firm that sells narcotic analgesics was able to use prescriber-identifiable data to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id*; *see also* Joint Appendix, Vol. II, *Sorrell v. IMS Health*, 2011 WL 687134, at *204 (Feb. 22, 2011).

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registrant actions between 2008 and 2012[408] and 117 recommended decision in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders – all for failure to report suspicious orders.[409]

576. Defendants' scheme had a decision-making structure driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the State and Federal Government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and identify suspicious orders and report them to the DEA.

577. The RICO Diversion Defendants worked together to control the flow of information and influence state and federal governments and political candidates to pass legislation that was pro-opioid. The Manufacturer and Distributor Defendants did this through their participation in the PCF and HDA.

578. The RICO Diversion Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

579. The scheme devised and implemented by the RICO Diversion Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against

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[408] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

[409] *Id.*

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diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

C. PATTERN OF RACKETEERING ACTIVITY.

580. The RICO Diversion Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(1)(D), including; the felonious manufacture, importation, receiving, concealment buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States; and 18 U.S.C. 1961(1)(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343).

1. <u>The RICO Diversion Defendants Manufactured, Sold and/or Dealt in Controlled Substances, and Their Actions Constitute Crimes Punishable as Felonies.</u>

581. The RICO Diversion Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(1)(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act).

582. The RICO Diversion Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of section 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

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583. Each of the RICO Diversion Defendants qualifies as a registrant under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in Schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

584. The CSA and the Code of Federal Regulations, require the RICO Diversion Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

585. The RICO Diversion Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA, including the Manufacturer Defendants' applications for production quotas. Specifically, the RICO Diversion Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

586. Upon information and belief, the foregoing examples reflect the RICO Diversion Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. The sheer volume of

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enforcement actions available in the public record against the Distributor Defendants supports this conclusion.[410] For example:

587. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration.

588. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone.

589. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone.

590. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone.

591. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone.

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[410] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

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592. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program."

593. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility").

594. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone.

595. On May 14, 2012, Cardinal Health entered into an Administrative Memorandum of Agreement with the DEA in which, among other things, Cardinal Health "admits that its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate."

596. Thereafter, on December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.

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597. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

598. In its Administrative Memorandum Agreement, McKesson acknowledged its wrongdoing and failure to comply with the obligations imposed by the CSA:

2. Acceptance of Responsibility. On or about September 27, 2006, February 7, 2007 and December 27, 2007, DEA's Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the period from January 1, 2009 up through and including the Effective Date of this Agreement (the "Covered Time Period"), it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its Controlled Substance Monitoring Program ("CSMP"). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

599. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay $150 million and have some of its DEA registrations suspended on a staggered basis.

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600. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles, yet failed to alert the DEA. The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. Documents published by the L.A. Times reveal that a Purdue sales manager spoke with company officials, asking: "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring."[411]

601. Purdue was clearly aware of diversion. As a registrant, Purdue has the same obligation to report suspicious orders as a wholesale distributor. Although Purdue claimed that it was considering making a report to the DEA, it shirked its responsibility, claimed that it was the wholesaler's responsibility and then reserved the right to make the report.

602. Despite its knowledge of obvious diversion, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about [a pill mill] until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."

603. Finally, Mallinckrodt was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012. After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a $35 million fine. Federal prosecutors summarized the case by saying that

[411] Harriet Ryan, et al., More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew., Los Angeles Times, July 10, 2016, http://ww.latimes.com/projects/la-me-oxycontin-part2/.

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Mallinckrodt's response was that everyone knew what was going on in Florida but they had no duty to report it.

604. These actions against the Distributor Defendants confirm that the Distributor Defendants knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

605. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

606. Many of the precise dates of the RICO Diversion Defendants' criminal actions at issue herein were hidden and cannot be alleged without access to their books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

607. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, Plaintiff's Community and the Plaintiff. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its residents or the Plaintiff. The Defendants were aware that Plaintiff and the residents of this jurisdiction rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

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608. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

609. The RICO Diversion Defendants' predicate acts and pattern of racketeering activity were a substantial and foreseeable cause of Plaintiff's injury, and the relationship between the RICO Diversion Defendants' conduct and Plaintiff's injury are logical and not speculative. It was foreseeable to the RICO Diversion Defendants that when they refused to identify, report and halt suspicious orders as required by the CSA and Code of Federal Regulations, it would allow the wide-spread diversion of prescriptions opioids into the illicit market and create an opioid-addiction epidemic that logically, substantially, and foreseeably harmed Plaintiff.

610. The RICO Diversion Defendants' predicate acts and pattern of racketeering activity were a substantial and foreseeable cause of Plaintiff's injury and the relationship between the RICO Diversion Defendants' conduct and Plaintiff's injury is logical and not speculative. It was also foreseeable to the RICO Diversion Defendants that when they fraudulently marketed highly-addictive and dangerous drugs, that were approved for very limited and specific uses by the FDA, as non-addictive and safe for off-label uses such as moderate pain, non-cancer pain, and long-term chronic pain, that the RICO Diversion Defendants would create an opioid-addiction epidemic that logically, substantially and foreseeably harmed Plaintiff.

611. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

2. <u>The RICO Diversion Defendants Engaged in Mail and Wire Fraud</u>.

612. The RICO Diversion Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public, by knowingly conducting or

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participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and interstate wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

613. The RICO Diversion Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Diversion Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Diversion Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The RICO Diversion Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

614. The RICO Diversion Defendants used, directed the use of, and/or caused to be used, thousands of mail and interstate wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

615. In devising and executing the illegal scheme, the RICO Diversion Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the RICO Diversion Defendants committed these

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racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

616. The RICO Diversion Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Diversion Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Diversion Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

617. The RICO Diversion Defendants' use of the mail and interstate wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of the RICO Diversion Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

c. Documents and communications that facilitated the manufacture, purchase and sale of prescription opioids;

d. Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated Defendants' DEA registrations;

f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

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g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Manufacturers;

k. Rebates and chargebacks from the Manufacturers to the Distributors;

l. Payments to Defendants' lobbyists through the PCF;

m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

618. On information and belief, the Manufacturer Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

619.

Defendant Group Name	**Company Names**	**Drugs**		
		Drug Name	**Chemical Name**	**CSA Schedule**
Purdue	(1) Purdue Pharma, LP, (2) Purdue Pharma, Inc., (3) The Purdue Frederick Company	OxyContin	Oxycodone hydrochloride extended release	Schedule II
		MS Contin	Morphine sulfate extended release	Schedule II
		Dilaudid	Hydromorphone hydrochloride	Schedule II
		Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
		Butrans	Buprenorphine	Schedule II

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		Hysinga ER	Hydrocodone bitrate	Schedule II
		Targiniq ER	Oxycodone hydrochloride	Schedule II
Cephalon	(1) Cephalon, Inc., (2) Teva Pharmaceutical Industries, Ltd., (3) Teva Pharmaceuticals USA, Inc.	Actiq	Fentanyl citrate	Schedule II
		Fentora	Fentanyl citrate	Schedule II
		Generec oxycontin	Oxycodone hydrochloride	Schedule II
Endo	(1) Endo Health Solutions, Inc., (2) Endo Pharmaceuticals Inc., (3) Qualitest Pharmaceuticals, Inc. (*wholly-owned subsidiary of Endo*)	Opana ER	Oxymorphone hydrochloride extended release	Schedule II
		Opana	Oxymorphone hydrochloride	Schedule II
		Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
		Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
		Generic oxycodone		Schedule II
		Generic oxymorphone		Schedule II
		Generic hydromorphone		Schedule II
		Generic hydrocodone		Schedule II
Mallinckrodt	(1) Mallinckrodt PLC, (2) Mallinckrodt LLC (*wholly-owned subsidiary of Mallinckrodt PLC*)	Exalgo	Hydromorphone hydrochloride	Schedule II
		Roxicodone	Oxycodone hydrochloride	Schedule II
Allergan	(1) Allergan Plc, (2) Actavis LLC, (3) Actavis Pharma, Inc., (4) Actavis Plc, (5) Actavis, Inc., (6) Watson Pharmaceuticals, Inc., Watson Pharma, Inc.	Kadian	Morphine Sulfate	Schedule II
		Norco (Generic of Kadian)	Hydrocodone and acetaminophen	Schedule II
		Generic Duragesic	Fentanyl	Schedule II
		Generic Opana	Oxymorphone hydrochloride	Schedule II

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620. Each of the RICO Diversion Defendants identified manufactured, shipped, paid for and received payment for the drugs identified above, throughout the United States.

621. The RICO Diversion Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Diversion Defendants made misrepresentations about their compliance with federal and state laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

622. At the same time, the RICO Diversion Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

623. Upon information and belief, the RICO Diversion Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

624. The RICO Diversion Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

625. The mail and interstate wire transmissions described herein were made in furtherance of RICO Diversion Defendants' scheme and common course of conduct to deceive regulators, the public and the Plaintiff that RICO Diversion Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while RICO Diversion Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Diversion Defendants' scheme and common course of

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conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

626. Many of the precise dates of the fraudulent uses of the mail and interstate wire facilities have been deliberately hidden by RICO Diversion Defendants and cannot be alleged without access to RICO Diversion Defendants' books and records. However, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

627. The RICO Diversion Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the RICO Diversion Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Diversion Defendants.

628. The RICO Diversion Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

629. The RICO Diversion Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the reality of the suspicious orders that the RICO Diversion Defendants were filling on a daily basis – leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit market.

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630. The RICO Diversion Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

631. Indeed, for the RICO Diversion Defendants' fraudulent scheme to work, each of the RICO Diversion Defendants had to agree to implement similar tactics regarding manufacturing prescription opioids and refusing to report suspicious orders.

632. As described herein, the RICO Diversion Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

633. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Diversion Defendants. The predicate acts were committed or caused to be committed by the RICO Diversion Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

634. The pattern of racketeering activity alleged herein and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, RICO Diversion Defendants are distinct from the enterprise.

635. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

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636. Many of the precise dates of the RICO Diversion Defendants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise alleged herein depended upon secrecy.

637. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff's Community and the Plaintiff. RICO Diversion Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on Plaintiff's Community, its residents or the Plaintiff. In designing and implementing the scheme, at all times RICO Diversion Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding RICO Diversion Defendants' products and their manufacture and distribution of those products. The RICO Diversion Defendants were also aware that Plaintiff and the residents of this jurisdiction rely on the RICO Diversion Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

638. By intentionally refusing to report and halt suspicious orders of their prescription opioids, RICO Diversion Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

639. It was foreseeable to RICO Diversion Defendants that Plaintiff would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the CSA and Code of Federal Regulations allowed the widespread diversion of

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prescription opioids out of appropriate medical channels and into the illicit drug market – causing the opioid epidemic that the CSA intended to prevent.

640. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

D. DAMAGES.

1. Impact of the Opioid Diversion Enterprise.

641. Plaintiff has suffered damages as described in paragraphs 67-87 above.

2. The Relief Sought.

642. The RICO Diversion Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property. The RICO Diversion Defendants' pattern of racketeering activity, including their refusal to identify, report and halt suspicious orders of controlled substances, logically, substantially and foreseeably cause an opioid epidemic. Plaintiff was injured by the RICO Diversion Defendants' pattern of racketeering activity and the opioid epidemic that they created.

643. The RICO Diversion Defendants knew that the opioids they manufactured and supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse.[412] Nevertheless, the RICO Diversion Defendants engaged in a scheme of deception, that utilized the mail and interstate wires as part of their fraud, in order to increase sales of their opioid

[412] *Traveler's Property Casualty Company of America v. Actavis, Inc.*, 22 Cal. Rptr. 3d 5, 19 (Cal. Ct. App. 2017).

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products by refusing to identify, report suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse, and were actually being diverted into the illegal market.[413]

644. Here, the link of causation generally breaks down into three very short steps: (1) the RICO Diversion Defendants' affirmative action to continue supplying prescription opioids through legal channels with knowledge that they were being diverted into the illicit market; (2) an opioid epidemic in the form of criminal drug trafficking, misuse and abuse; and (3) injuries to the Plaintiff.[414] This causal chain is a "direct sequence" and a logical, substantial and foreseeable cause of Plaintiff's injury.[415]

645. Specifically, the RICO Diversion Defendants' predicate acts and pattern of racketeering activity caused the opioid epidemic which has injured Plaintiff in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic. Plaintiff's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a. Losses caused by purchasing and/or paying reimbursements for the RICO Diversion Defendants' prescription opioids, that Plaintiff would not have paid for or purchased but for the RICO Diversion Defendants' conduct;

b. Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

c. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

d. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;

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[413] *City of Everett v. Purdue Pharma L.P.*, 2017 WL 4236062, *6 (W.D. Wash. Sept. 25, 2017).

[414] *Id.*

[415] *Id.*

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e. Costs associated with providing police officers, firefighters, and emergency and/or first responders with Naloxone – an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

f. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

g. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;

646. Plaintiff's injuries were proximately caused by RICO Diversion Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiff's injuries. But for the opioid-addiction epidemic created by RICO Diversion Defendants' conduct, Plaintiff would not have lost money or property.

647. Plaintiff's injuries were directly caused by the RICO Diversion Defendants' pattern of racketeering activities.

648. Plaintiff is most directly harmed and there are no other plaintiffs better suited to seek a remedy for the economic harms at issue here.

649. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT IV

RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT 18 U.S.C. § 1962(d), *et seq.* (Against All Defendants)

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650. Plaintiff hereby incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

651. Plaintiff brings this claim on its own behalf against all RICO Diversion Defendants. At all relevant times, the RICO Diversion Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d) it is unlawful for "any person to conspire to violate" Section 1962(d), among other provisions. 18 U.S.C. § 1962(d).

652. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference below.

A. THE OPIOID DIVERSION ENTERPRISE.

653. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the "Opioid Diversion Enterprise."

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE.

654. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the "Conduct of the Opioid Diversion Enterprise."

C. PATTERN OF RACKETEERING ACTIVITY.

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655. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the "Pattern of Racketeering Activity."

D. DAMAGES.

656. The RICO Diversion Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property because Plaintiff paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

657. Plaintiff's injuries, and those of its residents, were proximately caused by the RICO Diversion Defendants' racketeering activities. But for the RICO Diversion Defendants' conduct, Plaintiff would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

658. Plaintiff's injuries and those of its residents were directly caused by the RICO Diversion Defendants' racketeering activities.

659. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

660. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

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COUNT V

NEGLIGENCE, NEGLIGENT MISREPRESENTATION, AND NEGLIGENCE PER SE
(Against All Defendants)

661. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

662. Plaintiff seeks economic damages which were the foreseeable result of the Defendants' intentional and/or unlawful actions and omissions.

663. Under State law, to establish actionable negligence, Plaintiff must show: "(1) that defendant's conduct caused a foreseeable risk of harm, (2) that the risk is to an interest of a kind that the law protects against negligent invasion, (3) that defendant's conduct was unreasonable in light of the risk, (4) that the conduct was a cause of plaintiff's harm, and (5) that plaintiff was within the class of persons and plaintiff's injury was within the general type of potential incidents and injuries that made defendant's conduct negligent." *Son v. Ashland Comm'y Healthcare Servs.*, 239 Or. App. 495, 506, 244 P.3d 835 (2010) (quoting *Solberg v. Johnson*, 306 Or. 484, 490-91, 760 P.2d 867 (1988)). All such essential elements exist here.

664. Additionally, Oregon law recognizes the doctrine of negligence per se when a statute creates a standard of care and the plaintiff is within the class of persons that the legislature intended protect, and the harm is the kind that the statute was intended to prevent. *See Kim v. Multnomah Cty. ex rel. Multnomah Cty. Cmty. Dept. of Cmty. Corrs.*, 328 Or. 140, 152, 970 P.2d 631 (1998).

665. Defendants breached their duties to maintain effective controls against diversion of dangerously-addictive opioids, including violating public safety statutes and regulations requiring that as wholesale drug distributors, Defendants could only distribute these dangerous drugs under a closed system – a system Defendants were responsible for guarding.

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666. Defendants' actions were not "authorized" by the Oregon Uniform Controlled Substances Act because Defendants did not comply with the mandatory terms of the licenses issued to them by the Oregon State Board of Pharmacy or with federal requirements incorporated by reference, as further detailed in this Complaint.

667. Defendants also violated Or. Rev. Stat. § 475.165, which provides that "persons registered to manufacture, deliver or dispense controlled substances . . . shall keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of federal law and with any additional rules the State Board of Pharmacy issues."

668. Defendants also violated regulations promulgated by the Oregon State Board of Pharmacy by violating the requirements for distributors to receive a license, including, *inter alia*, complying with "applicable federal, state, and local laws and regulations." Or. Admin. Code § 855-065-0010(8).

669. The Oregon Uniform Controlled Substances Act further provides that "[a]ny penalty imposed for violation . . . is in addition to, and not in lieu of, any civil or administrative penalty or sanction otherwise authorized by law." Or. Rev. Stat. § 475.255.

670. The Oregon Legislature authorized the Oregon State Board of Pharmacy to govern the registration of applicants and specify through regulations precisely how the manufacturers and distributors were to comply with the Oregon Uniform Controlled Substances Act. Or. Rev. Stat. § 475.125; Or. Rev. Stat. §475.135; Or. Rev. Stat. §475.145; and Or. Rev. Stat. § 689.155.

671. Thus, violations of the rules implementing the Oregon Uniform Controlled Substances Act, to the extent that they were intended to protect public safety, are a basis for the imposition of civil liability under Oregon law.

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672. Plaintiff is within the class intended to be protected by the public safety statutes and regulations concerning controlled substances.

673. Defendants' violations of these public safety laws are prima facie evidence of negligence per se. Each Defendant had a duty under, *inter alia*, these laws to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids. Defendants' violations of the law constitute negligence per se. Defendants breached mandatory, non-delegable legal duties and did not act reasonably under the circumstances.

674. As described above in allegations expressly incorporated herein, Defendants' breach of statutory and regulatory duties caused, bears a causal connection with, is and was a substantial factor contributing to, and/or proximately resulted in, harm and damages to Plaintiff.

675. The injuries and damages sustained are those which the Oregon statutes and regulations were designed to prevent.

676. Even without a statutory framework, Defendants should have reasonably foreseen the risk of probable harm as a result of their negligence. *See Piazza v. Kellim*, 377 P.3d 492, 499-500 (Or. 2016). Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and impose significant costs upon the governmental entities associated with those communities.

677. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly-addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids, frequently turning to the illegal drug market as a result of a drug addiction that was foreseeable to the Manufacturer Defendants.

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678. The risk of harm was of the specific kind that the law protects against, as each Defendant had an obligation to exercise reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs to the State and Plaintiff's Community.

679. Defendants' failure to follow the laws for manufacturing, marketing, selling, and distributing highly dangerous opioid drugs to the State and Plaintiff's Community and their deceptive marketing of these dangerous opioid drugs was unreasonable in light of the risk.

680. Defendants' acts and omissions were a substantial factor in causing harm to Plaintiff.

681. Moreover, law enforcement repeatedly warned Defendants of the unlawfulness and consequences of their actions and omissions.

682. As described above in allegations expressly incorporated herein, Defendants' breaches of duty and misrepresentations caused, bear a causal connection with and/or proximately resulted in the damages sought herein.

683. The Defendants' breaches of their duties and misrepresentations were the cause-in-fact of Plaintiff's injuries.

684. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the Defendants' actions and omissions.

685. Plaintiff seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

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COUNT VII

FRAUD AND FRAUDULENT MISREPRESENTATION
(Against All Defendants)

686. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

687. In Oregon, the tort of fraud or intentional misrepresentation has the following elements: "(1) a representation; (2) its falsity; (3) its materiality; (4) the speaker's knowledge of its falsity or ignorance of its truth; (5) his intent that it should be acted on by the person and in the manner reasonably contemplated; (6) the hearer's ignorance of its falsity; (7) his reliance on its truth; (8) his right to rely thereon; and (9) his consequent and proximate injury." *Burgdorf v. Weston*, 259 Or. App. 755, 771, 316 P.3d 303, 313 (2013).

688. Defendants violated their general duty not to actively deceive, have made knowingly false statements and have omitted and/or concealed information which made statements Defendants did make knowingly false. Defendants acted intentionally and/or unlawfully.

689. As alleged herein, Defendants made false statements regarding their compliance with state and federal law regarding their duties to prevent diversion, their duties to monitor, report and halt suspicious orders, and/or concealed their noncompliance with these requirements.

690. As alleged herein, the Manufacturer Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic, non-cancer pain.

691. As alleged herein, the Defendants knowingly and/or intentionally made representations that were false. Defendants had a duty to disclose material facts and concealed them. These false representations and concealed facts were material to the conduct and actions at issue. Defendants made these false representations and concealed facts with knowledge of the

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falsity of their representations, and did so with the intent of misleading Plaintiff, Plaintiff's Community, the public, and persons on whom Plaintiff relied.

692. These false representations and concealments were reasonably calculated to deceive Plaintiff, Plaintiff's Community, and the physicians who prescribed opioids for persons in Plaintiff's Community, were made with the intent to deceive, and did in fact deceive these persons, Plaintiff, and Plaintiff's Community.

693. The physicians who prescribed opioids reasonably relied on these false representations and concealments of material fact.

694. Plaintiff justifiably relied on Defendants' representations and/or concealments, both directly and indirectly. Plaintiff's injuries were proximately caused by this reliance.

695. The injuries alleged by Plaintiff herein were sustained as a direct and proximate cause of the Defendants' fraudulent conduct.

696. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent activity, including fraudulent misrepresentations and fraudulent concealment.

697. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory damages and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

COUNT VIII

UNJUST ENRICHMENT
(Against All Defendants)

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698. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege as follows.

699. Oregon law recognizes the legal standard set forth in the Restatement (3d) Restitution § 13 comment a, at 166, that "a conclusion that one party has obtained benefits from another by fraud is one of the most recognizable sources of unjust enrichment." *Larisa's Home Care, LLC v. Nichols-Shields*, 326 Or. 115, 133, 404 P.3d 912 (Or. 2017).

700. Plaintiff conferred on each Manufacturing Defendant a benefit, including payments for opioids manufactured by the Manufacturing Defendants for sale in the City of Portland, which benefit was known to and accepted by each Manufacturing Defendant, which inured to the profits of each Manufacturing Defendant and for which retention of such benefit is inequitable based on the Manufacturing Defendants' false and misleading marketing and omissions of and failure to state material facts in connection with marketing opioids, as set forth herein. The Manufacturing Defendants have thus been unjustly enriched by deceptive marketing, contributing to the City of Portland's current opioid epidemic.

701. Plaintiff conferred on each Distributor Defendant a benefit, including payment for opioids distributed by each Distributor Defendant for sale in the City of Portland, which benefit was known to and accepted by each Distributor Defendant, which inured to the profits of each Distributor Defendant and for which retention of such benefit is inequitable based on the Distributor Defendants' failure to report suspicious sales as required by law. The Distributor Defendants have thus been unjustly enriched by neglecting their duty to distribute drugs only for proper medical purposes, contributing to the City of Portland's current opioid epidemic.

702. The City of Portland's unprecedented opioid addiction and overdoes epidemic has cost millions of dollars in health insurance, emergency services, self-insured medical payments

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and lost productivity within its work force, law enforcement, and other services for Plaintiff's community.

703. The unjust enrichment of the Manufacturing Defendants and Distributor Defendants is directly related to the damage, loss and detriment of City of Portland caused by Defendants' false marketing and failure to report suspicious sales. It would be inequitable under these circumstances for the Manufacturing Defendants and Distributor Defendants to retain this benefit without compensating Plaintiff for their value. Plaintiff seeks recovery of the amounts the Manufacturing Defendants and Distributor Defendants were enriched as a result of their inequitable conduct.

PUNITIVE DAMAGES

704. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

705. As authorized by Or. Rev. Stat. § 31.725, Plaintiff reserves its right to amend this complaint to add claims for punitive damages.

RELIEF

WHEREFORE, the Plaintiff respectfully prays that this Court grant the following relief:

706. Entering Judgment in favor of the Plaintiff in a final order against each of the Defendants;

707. Order that Defendants compensate the Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic, including restitution;

708. Order Defendants to fund an "abatement fund" for the purposes of abating the opioid nuisance;

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709. Awarding actual damages, treble damages, injunctive and equitable relief, forfeiture as deemed proper by the Court, and attorney fees and all costs and expenses of suit pursuant to Plaintiff's racketeering claims;

710. Awarding the Plaintiff the damages caused by the opioid epidemic, including (A) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for Health Plan Members suffering from opioid-related addiction or disease, including overdoses and deaths; (B) costs for providing treatment, counseling, and rehabilitation services associated with housing and criminal justice programs; (C) costs associated with emergency services used to respond to opioid overdoses; and (D) costs associated with law enforcement and public safety relating to the opioid epidemic.

711. Enter a judgment against the Defendants requiring Defendants to pay punitive damages and granting the Plaintiff:

1. Economic damages.
2. The cost of investigation, reasonable attorneys' fees, and all costs and expenses, including reasonable attorneys' fees and costs pursuant to the Common Fund Doctrine;
3. Pre-judgment and post-judgment interest; and,
4. All other relief as provided by law and/or as the Court deems appropriate and just.

Dated: May 10, 2018

Respectfully Submitted,

CITY OF PORTLAND, Plaintiff

By: /s/J. Scott Moede
J. Scott Moede, OSB No. 934816
Chief Deputy City Attorney

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